The Health Economics of Obesity and Bariatric Surgery

By

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BEc (Hons), Grad Cert (Research)

A thesis submitted in fulfilment of the requirements for the degree of Doctor of Philosophy (Medical Research)

University of Tasmania, Australia

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Dedicated to my son, Anthony.

In loving memory of, and dedicated to my parents,

Wayne and Shirley Campbell.

Declaration of originality

This thesis contains no material which has been accepted for a degree or diploma by the University or any other institution, except by way of background information and duly acknowledged in the thesis, and to the best of my knowledge and belief no material previously published or written by another person except where due acknowledgement is made in the text of the thesis, nor does the thesis contain any material that infringes copyright.

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Statement of co-authorship

This thesis includes seven papers for which Julie Anne Campbell (JC) is the first but not sole author. JC led the work in developing and conceptualising the papers, collecting/extracting the data, implementing the analyses and writing the manuscripts under the primary supervision of Andrew J Palmer (AP), secondary supervisor Alison Venn (AV) and third supervisor Amanda Neil (AN). Throughout the work presented herein she was assisted by co-authors from research alliances. Detailed below are the contributions from each author.

1. Paper presented in Chapter 2

Campbell JA, Venn A, Neil A, Hensher M, Sharman M, Palmer AJ. Diverse approaches to the health economic evaluation of bariatric surgery: a comprehensive systematic review. *Obesity Reviews*. 2016 Sep;17(9):850-94. doi: 10.1111/obr.12424. Epub 2016 Jul 7.

Contribution from each author:

- JC developed the protocol following the Campbell Cochrane Economic Methods Group, the PRISMA Statement and the Consolidated Health Economic Evaluation Reporting Statement (for the quality appraisal). JC performed the data collection, extraction and narrative synthesis and interpretation of the results of the narrative synthesis. JC compiled the manuscript and manuscript revisions for submission.
- AP was involved in the conceptualisation, development and drafting of the protocol, validation of data extracted for narrative synthesis, along with the interpretation of the results and manuscript revisions.
- AV was involved in conceptualising the paper, interpretation of results and manuscript revisions.

- AN was involved in conceptualising the paper, interpretation of results and manuscript revisions.
- MH was involved in conceptualising the paper, interpretation of results and manuscript revisions.
- MS assisted with paper screening and validation of included studies and was involved in manuscript revisions.

2. Paper presented in Chapter 3

Campbell JA, Palmer AJ, Venn A, Sharman M, Otahal P, Neil A. A Head-to-head comparison of the EQ-5D-5L and AQoL-8D multi-attribute utility instruments in patients who have previously undergone bariatric surgery. *The Patient – Patient Centered Outcomes Research.* 2016 Aug;9(4):311-22. doi: 10.1007/s40271-015-0157-5.

Contribution from each author:

- JC conceptualised the study, assisted with ethics approvals, undertook the study design, data extraction, data verification, data analysis and data interpretation, compiled the manuscript and coordinated manuscript revisions and submission.
- AN assisted with the conceptualisation of the study, contributed to the study design, data analysis and interpretation, and manuscript revisions.
- AP assisted with the conceptualisation of the study, contributed to the study design and data interpretation, and manuscript revisions.
- AV contributed to the study design and data interpretation, and manuscript revisions.
- PO contributed to the data analysis and manuscript revisions.
- MS collected the survey forms from focus group participants and validated the data extraction from the survey forms, and contributed to the manuscript revisions.

3. Paper presented in Chapter 4

Campbell JA, Hensher M, Neil A, Venn A, Wilkinson S, and Palmer AJ. An Exploratory Study of Long-Term Publicly Waitlisted Bariatric Surgery Patients' Quality of Life Before and 1 Year After Bariatric Surgery, and Considerations for Healthcare Planners. *PharmacoEconomics-Open*. 2017. doi:10.1007/s41669-017-0038-z

Contribution from each author:

- JC conceptualised the study, undertook the study design, undertook recruitment of the cohort, assisted with ethics approvals, collected and managed the data for analysis, extracted the data from survey forms and administrative databases, extracted biomedical data from medical records, verified the data, conducted data analysis and data interpretation, compiled the manuscript and coordinated manuscript revisions and submission.
- AP conceptualised the study, contributed to the study design and data interpretation, and manuscript revisions.
- MH conceptualised the study, and contributed to data verification and interpretation, and manuscript revisions.
- AV conceptualised the study, contributed to the study design, assisted with data interpretation and manuscript revisions.
- AN contributed to the data interpretation and manuscript revisions.
- SW conceptualised the study, was the surgeon for the cohort, assisted with data interpretation and manuscript revisions.

4. Paper presented in Chapter 5

Campbell JA, Hensher M, Neil A, Venn A, Otahal P, Wilkinson S, and Palmer AJ. An exploratory study: a head-to-head comparison of the EQ-5D-5L and AQoL-8D for long-term publicly waitlisted bariatric surgery patients before and 3 months after bariatric surgery. *PharmacoEconomics – Open*. 2017. doi: 10.1007/s41669-017-0060-1

Contribution from each author:

- JC conceptualised the study, undertook the study design, undertook recruitment of the cohort, assisted with ethics approvals, collected and managed the data, extracted data from survey forms and administrative databases, extracted biomedical data from medical records, verified the data, conducted data analysis and data interpretation, compiled the manuscript and coordinated manuscript revisions and submission.
- AP conceptualised the study, contributed to the study design and data interpretation, and manuscript revisions.
- MH conceptualised the study, and contributed to data verification and interpretation, and manuscript revisions.
- AV conceptualised the study, contributed to the study design, assisted with data interpretation and manuscript revisions.
- AN contributed to data interpretation and manuscript revisions.
- PO contributed to the data analysis and manuscript revisions.
- SW conceptualised the study, was the surgeon for the cohort, assisted with data interpretation and manuscript revisions.

5. Paper presented in Chapter 6

Campbell JA, Ezzy D, Neil A, Hensher M, Venn A, Sharman MJ, and Palmer AJ. A qualitative investigation of the health economic impacts of bariatric surgery for obesity, and implications for improved practice in health economics. *Health Economics*. 2018 Aug;27(8):1300-1318.

Contribution from each author:

- JC conceptualised the study, developed and undertook the study design, assisted with the ethics approvals, coordinated the development of health economic topics and questions for the focus group discussion schedule before and throughout the data acquisition from focus groups, analysed and interpreted the qualitative data with pre-existing economic theory, compiled the manuscript and coordinated manuscript revisions and submission.
- AP assisted with the conceptualisation of the study, contributed to the study design, assisted with the interpretation of the qualitative results and critically reviewed the manuscript and revisions.
- DE contributed to the study design, collected the focus group data, assisted with the interpretation of the qualitative results, and critically reviewed the manuscript and revisions.
- AN contributed to the study design and assisted with the manuscript revisions.
- MH contributed to the study design and assisted with the manuscript revisions.
- AV contributed to the study design, assisted with data acquisition, and assisted with the manuscript revisions.
- MS contributed to the study design, coordinated the ethics approvals, assisted with the data acquisition, and assisted with the manuscript revisions.

6. Paper presented in Chapter 7

Campbell JA, Ezzy D, Hensher M, Neil A, Venn A, Sharman MJ, Wilkinson S and Palmer AJ. A qualitative investigation of information asymmetry for obesity surgery: diversity of patient experiences in the information age and demand-induced supply.

Contribution from each author:

- JC conceptualised the study, developed and undertook the study design, assisted with the ethics approvals, coordinated the development of health economic topics and questions for the focus group discussion schedule before and throughout the data acquisition from focus groups, analysed and interpreted the qualitative data with pre-existing economic theory, compiled the manuscript and coordinated manuscript submission.
- AP assisted with the conceptualisation of the study, contributed to the study design, assisted with the interpretation of the qualitative results and critically reviewed the manuscript.
- DE contributed to the study design, collected the focus group data, assisted with the interpretation of the qualitative results, and critically reviewed the manuscript.
- AN assisted with the conceptualisation of the study and assisted with the manuscript revisions.
- MH assisted with the conceptualisation of the study and assisted with the manuscript revisions.
- AV contributed to the study design, assisted with data acquisition, and assisted with the manuscript revisions.
- MS contributed to the study design, coordinated the ethics approvals, assisted with the data acquisition, and assisted with the manuscript revisions.
- SW contributed to the study design and assisted with manuscript revisions

7. Paper presented in Chapter 8

Campbell JA, Hensher M, Davies D, Green M, Hagan B, Jordan I, Venn A, Kuzminov A, Neil A, Palmer AJ. A cost-outcome study: A real-world investigation of long-term inpatient hospital utilisation and costs for a retrospective cohort of bariatric surgery patients in an Australian public hospital system based on Australia's Activity Based Funding model.
Contribution from each author:

- JC conceptualised the study and developed and coordinated the strategic research alliance for the study with the project partner. JC coordinated the initial ethics approvals. JC developed and undertook the study design. JC coordinated and managed the data extracted for analysis, analysed and interpreted the data and compiled the manuscript for submission.
- AP assisted with the conceptualisation of the study and the study design, assisted with the interpretation of the findings and critically reviewed the manuscript.
- DD contributed to the study design, extracted the raw cost data, validated the final cohort and data for analysis, and developed the cost database for data management.
- MG assisted with the initial data capture for analysis, assisted with the extraction of cost data and the development of the cost database for data management.
- BH assisted with the extraction of cost data and the development of the cost database for data management.
- IJ contributed to the study design and reviewed the manuscript.
- AV assisted with the conceptualisation of the study and the study design, assisted with the interpretation of the findings and critically examined the manuscript.
- AK assisted with the conceptualisation of the study, collected the BMI data from medical records, validated the surgical sequelae from medical records as requested by JC, and reviewed the manuscript.
- AN assisted with the conceptualisation of the study and the study design and critically reviewed the manuscript.
- MH assisted with the conceptualisation of the study and the strategic research alliance, assisted with the interpretation of the findings and critically examined the manuscript.

Signed

Date: 14.12.17	12.12.17
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Statement of ethical conduct

The research associated with this thesis abides by the international and Australian codes on human and animal experimentation, the guidelines by the Australian Government's Office of the Gene Technology Regulator and the rulings of the Safety, Ethics and Institutional Biosafety Committees of the University.

Signature

14.12.2017

Julie A. Campbell

Date

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Finally I dedicate this thesis to my beautiful son Anthony. You inspire me every day with your love of life and your attitude to take things in your stride and have a go at life. Children are the markers of time: when I commenced my PhD you were only 6 years old and could not read – now you are 10 and ask me 'can I read your book mum?' Well dearest and beautiful Anthony, the 'book' is complete but I don't expect that you will read it just yet – maybe when you're an adult. If you do read it when you're all grown-up, please know that without your unconditional love and support I would not have made it through the past 4 years.

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Abstract

Background: Obesity is not only a major health concern, it is an economic problem. The current rates of obesity (defined as body mass index (BMI) ≥ 30 kg/m²) are epidemic and severe obesity (defined as BMI ≥ 35 kg/m²) is increasing more rapidly than obesity. Treatments for overweight and obesity include dietary therapy, exercise/behavioural interventions, weight loss medications and bariatric surgery. Bariatric surgery is considered the most efficacious intervention for severe and resistant obesity.

This PhD thesis titled 'The Health Economics of Obesity and Bariatric Surgery' is an important part of a comprehensive, mixed-methods and multi-disciplinary Australian National Health and Medical Research Council (NHMRC) partnership project regarding bariatric surgery as a treatment option for obesity, within the State of Tasmania (Australia), nationally, and internationally. Key health economic evidence gaps were initially identified in the development of the successful NHMRC partnership project grant proposal.

Aims: As a health economist within the NHMRC partnership project team, the principal aims of my PhD research were to: provide critical baseline analyses of the key themes and evidence gaps regarding the health economic reporting of bariatric surgery, locally, nationally and internationally; address key evidence gaps regarding the physical and psychosocial domains of health-related quality of life from the time of waitlisting for bariatric surgery; establish the multi-attribute utility instrument that preferentially captures the physical and psychosocial health-related quality of life of people waiting for, or who have undergone bariatric surgery; use qualitative research methods to investigate bariatric surgery patients' experiences to identify and prioritise health economic impacts of bariatric surgery that are typically excluded from existing studies, or not provided with sufficient priority; and develop a strategic research alliance with our Tasmanian State Government project partner to investigate the resource use and costs of obesity and bariatric surgery to the Tasmanian public hospital system.

Methods: This thesis adopted a mixed-methods approach within real-world policy settings, consistent with a call for health economists to implement mixed-methods and policy-relevant research that is embedded in, and derived from real-world policy settings.

First, validated guidelines and methodologies were followed in the systematic selection and analyses of the published literature regarding the health economic evaluation of bariatric surgery. The findings of this comprehensive systematic review informed the methods of the remainder of the thesis (Chapter 2).

Second, the vastly different EQ-5D-5L and AQoL-8D multi-attribute utility instruments were systematically selected to investigate health state utility valuations (both instruments) and individual and super dimension scores (AQoL-8D only) in two cohorts of bariatric surgery patients. Patients who had received bariatric surgery many years previously in the private healthcare system (cross-sectional - Chapter 3) and patients who were publicly waitlisted for their surgery for many years and then operated on as part of a government policy decision to reduce waiting lists (longitudinal - Chapters 4 and 5) were studied.

Third, qualitative research methods were used to investigate bariatric surgery patients' 'lived' experiences to identify and prioritise health economic impacts of bariatric surgery that are typically excluded from existing studies (Chapters 6 and 7).

Fourth, a strategic research alliance with the critical health and project partner was adopted to construct and analyse a Tasmanian public hospital resource use and cost database about publicly-waitlisted patients before and after their primary bariatric surgery and surgical sequelae (Chapter 8).

Thesis outline and summary of key results:

Chapter 1 presents a general introduction of the health and economic burden of the obesity epidemic and bariatric surgery as a treatment option, and health economic concepts pertinent to this thesis.

Chapter 2 provides a published comprehensive systematic review of the health economic evaluation of bariatric surgery. Evidence gaps identified in the systematic review informed the direction of the subsequent PhD projects of this thesis, part of the work program for the NHMRC partnership project, and some of the future directions for research beyond this thesis. Among other things, this study found that only 13% of included studies adopted a broader societal perspective, the cost of complications and reoperations for bariatric surgery were not included in one-third of studies and when they were included conservative estimates were generally adopted, out-of-pocket costs were largely ignored, the EQ-5D suite of multi-attribute utility instruments was prevalent in the health economic evaluation of bariatric surgery, and that only one study investigated publicly waitlisted patients. The study's quality appraisal against the Consolidated Health Economic Evaluation Reporting Standards checklist found heterogeneous approaches, inconsistent quality and key evidence gaps in the health economic reporting of bariatric surgery.

Chapters 3, 4 and 5 present the first integrated published suite of health-related quality of life studies for the bariatric surgery study population that systematically selected two markedly different multi-attribute utility instruments, namely the EQ-5D-5L (Chapter 2 established the EQ-5D-5L was the internationally prevalent instrument in the economic evaluation of bariatric surgery) and the AQoL-8D (based on psychometric principles and testing). Importantly, the two instruments were used and compared for two different cohorts of bariatric surgery patients.

Chapter 3 provides the first head-to-head comparison of the EQ-5D-5L and AQoL-8D for a cross-sectional cohort of patients who had received bariatric surgery in the private healthcare sector many years previously (median (interquartile range) 5 (3-8) years). Chapter 3 found that psychosocial health was a key driver for the study population and that the AQoL-8D preferentially captured and assessed their psychosocial health. This study also explored the international dominance of the EQ-5D in the clinical and economic evaluation literature and the paper recommended that the choice of multi-attribute utility instrument should be influenced by the innate sensitivities of the instrument to the relevant domains of heath for the particular study population.

Chapters 4 and 5 were the first studies to use the EQ-5D-5L and AQoL-8D for a unique cohort of long-term and severely obese publicly waitlisted patients who then received bariatric surgery due to a public policy decision to reduce waiting lists. Chapter 2 identified that only one health economic study investigated the impact of waiting for bariatric surgery. A key finding of these studies was that the preoperative AQoL-8D health state utility valuation for this increasingly prevalent subgroup of bariatric surgery patients was less than those of people with cancer or heart disease. Even 3 months, and then 1 year after bariatric surgery, long-term publicly waitlisted patients recorded significant and clinically meaningful health-related quality of life improvements. This result suggested that long-waiting patients should not be 'written-off' by healthcare decision makers: they can still realise significant improvements in health-related quality of life outcomes when ultimately treated, and this should be factored into patient prioritisation decisions. Chapters 4 and 5 also investigated the emerging literature regarding the predictive capabilities of multi-attribute utility instruments in patient-centred bariatric care.

Chapters 6 and 7 present studies that harness the unique advantages of qualitative research methods to improve our practice in health economics. The inspiration for the method of these studies was partly directed by the systematic review (Chapter 2) that identified the limited scope of costs and consequences for most health economic evaluations of bariatric surgery. Additionally, there has been a call for health economists to effectively integrate combinations of qualitative and quantitative methods into their research toolkit to enrich their research methodologies and therefore improve their practice in health economic study design, data gathering and analysis, reporting and ultimately research translation. These studies listened to patients' stories and key themes were identified inductively through a dialogue between the qualitative focus group data and pre-existing economic theory (perspective; externalities; emotional capital; information asymmetry). Published Chapter 6 identified the concept of emotional capital as a 'potentiator' for human capital where participants described life-changing desires to be productive and participate in their communities postoperatively. Two-thirds of the focus group participants accessed private healthcare for bariatric surgery and some of these participants experienced substantial economic burden to do so.

Chapter 7 presents a second health economics study that implemented qualitative research methods. The inspiration for this study was that a key market failure in healthcare is information asymmetry. However, in the information-age, bariatric surgery patients may be more empowered in their negotiated relationship with healthcare providers through demand-induced supply. This study found a divergence between the pre- and postoperative information drivers. Psychosocial or socio-emotional drivers informed the sources and types of information that were important to participants preoperatively. The study also found that information sources relevant to participants preoperatively (e.g. family and friends, and the Internet) were different postoperatively (surgeon, allied-health professionals e.g. psychologist).

Chapter 8's quantitative study is the final paper of this mixed-methods PhD thesis. This hospital inpatient resource use and costing study is the first study within the Australian public hospital setting to report on individual episodes-of-care and costed patient-level pathways for primary bariatric surgery, and surgical sequelae including secondary/tertiary surgery informed by Australia's Activity Based Funding model. Chapter 2 guided the study's investigation of the patient-level costs, the costs of waiting for bariatric surgery, subgroup analyses (patients with diabetes and cardiovascular disease), and the accurate cost of complications and reoperations over a long time horizon. Chapter 8 found that the cost of providing primary laparoscopic

adjustable gastric band surgery in Tasmanian public hospitals compared with the sleeve gastrectomy procedure is similar. The study also suggested that prevalent laparoscopic adjustable gastric band device-related costs could be mitigated with alternative surgical methods such as sleeve gastrectomy within the Tasmanian public hospital system. Subgroup analyses revealed that for people with diabetes, the average cost for an episode-of-care reduced from year 1 after surgery.

Principal conclusions: Overall, this thesis provided a broader societal perspective regarding bariatric surgery as a treatment option for obesity. There is disparate health economic evaluation and reporting of bariatric surgery of inconsistent quality. Partial and full health economic evaluations of bariatric surgery generally populate their models with a narrow spectrum of short-term direct medical cost data regarding the primary surgery only from administrative databases. The AQol-8D preferentially captures physical and psychosocial health for the study population and this finding has implications for the cost-utility analyses of bariatric surgery. Long-term waitlisted patients realise significant health state utility valuation improvements (and individual and super dimension scores for the AQoL-8D) even three months after bariatric surgery suggesting that these patients should not be 'written-off' by healthcare planners if significant health benefits can be realised when they are ultimately treated. Qualitative research methods revealed the importance of emotional capital and out-of-pocket costs, and the sources and types of information before and after bariatric surgery. Bariatric surgery in the Tasmanian public hospital system may be an attractive value-based option in the longer term: bariatric surgery realised health benefits (reduced inpatient episodes-of-care) and reduced costs at year 3 postoperatively. Laparoscopic adjustable gastric band device-related costs could be mitigated if replaced with sleeve gastrectomy bariatric surgery where clinically appropriate

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Abbreviations

ABF	Activity Based Funding (Australia)
ABS	Australian Bureau of Statistics
AIHW	Australian Institute of Health and Welfare
AQoL-8D	Assessment of Quality of Life - eight dimension
DHHS	Department of Health and Human Services (Tasmania, Australia)
EoC	Episode of care
EQ-5D-5L	EuroQol five dimension five level
HRQoL	Health-related quality of life
HSUV	Health state utility valuation
IHPA	Independent Hospital Pricing Authority (Australia)
LAGB	Laparoscopic adjustable gastric band
MAUI	Multi-attribute utility instrument
NHMRC	National Health and Medical Research Council (Australia)
NICE	National Institute for Health and Care Excellence (United Kingdom)
OECD	Organization for Economic Cooperation and Development
PRO	Patient-reported outcome
SG	Sleeve gastrectomy
WHO	World Health Organization

Table of Contents

Chapter 1 - General introduction and outline:

The health economics of obesity and bariatric surgery.

1.1 National Health and Medical Research Council partnership project

Economics is one of several social sciences that attempt to explain and predict human behaviour, however, it is unique among the social sciences in establishing a concept of scarcity and uncertainty: economics is concerned with the way scarce resources are allocated among alternative uses to satisfy unlimited human wants [1]. Health economics, as a highly specialised and separate discipline, is both guided by and, more importantly, challenges (both philosophically and methodologically) aspects of economic (particularly neoclassical economic) orthodoxy.

My economics undergraduate and honours degrees were based on the neoclassical quantitative economist's toolkit. However, the qualitative component of my mixed-methods health economic PhD research and this thesis regarding obesity and bariatric surgery has encouraged me to consider the *human stories* (and therefore the human behaviour) that inform any health economic study concerning people with obesity and their experiences before and after their bariatric surgery. My previous background as Registered Nurse has also enabled me to reflect on these patients' narratives.

This PhD research and thesis are part of a comprehensive, mixed-methods and multi-disciplinary Australian National Health and Medical Research Council (NHMRC) partnership project regarding bariatric surgery as a treatment option for obesity, within Tasmania (a state of Australia), Australia, and internationally.

The NHMRC partnership project comprises academic researchers from wide-ranging disciplines, clinicians, government policy decision-makers and allied-health practitioners. My PhD research commenced through the collaborative effort between myself and my key supervisors and the project team.

Our Tasmanian State Government project partners stated that 'the burden of morbid obesity on individuals, government and society is unclear and the allocation of public resources to bariatric surgery lacks a strong evidence base'. Consequently, my initial health economic investigation identified that there were key knowledge gaps in the health economics reporting of bariatric surgery in Tasmania, nationally and internationally. The key objective of my PhD research was to address these pressing health economic knowledge and policy gaps for people with obesity waiting for, and/or who had received bariatric surgery, our project partners, the health economics community, the healthcare systems and society.

My PhD research thesis also aimed to identify the most promising opportunities for future research.

This introductory chapter will provide background regarding the obesity epidemic and bariatric surgery as a treatment intervention from an epidemiological and public health perspective. The chapter then explores the important health economic concepts that guide this thesis, the health economic burden of obesity and key evidence gaps regarding the health economic investigation of bariatric surgery. The chapter concludes with a summary of the methods and structure of this thesis, the aims of this thesis, and scholarly output as a direct result of this thesis.

1.2 An introduction to obesity

Obesity is a not only a public health problem, it is an economic problem [2-9].

Overweight and obesity are defined by the World Health Organization (WHO) as '*abnormal* *or excessive fat accumulation that may impair health'* [10]. The WHO also notes that body mass index (BMI) is a simple index of weight-for-height that is commonly used to classify overweight and obesity in adults. BMI is defined as a person's weight in kilograms (kg) divided by the square of his/her height in metres (m), BMI = weight (kg)/height² (m²). For adults, the WHO defines overweight and obesity as follows:

- overweight is a BMI ≥ 25 kg/m²; and
- obesity is a BMI ≥ 30 kg/m² [10].

Notwithstanding debate in the published literature regarding the accuracy of BMI as a measure of obesity, most clinical, epidemiological and health economics research defines obesity using BMI as the key measure [11-13]. It has been proposed that social science research would be enriched by greater consideration of alternate specifications of weight and height and more accurate measures of body fat [12, 13]. For example, a recent study that investigated whether or not the association between fat mass and employment status vary by anthropometric measures (measured rather than self-report height and weight (BMI) and waist-circumference) based on data from 15 rounds (1998-2013) of the Health Survey of England, concluded that the consequences of obesity for employment were larger when waist-circumference was used as a measure for obesity compared with BMI in the study's non-instrumental variable models [13].

For children and adolescents the WHO states that in infants and children under 5 years of age, obesity is assessed according to the WHO 'Child Growth Standards' (weight-for-length, weight-for-height) and the WHO Reference for 5-19 years (BMI-for-age) [10]. However, the studies contained in this thesis all concern adult study populations.

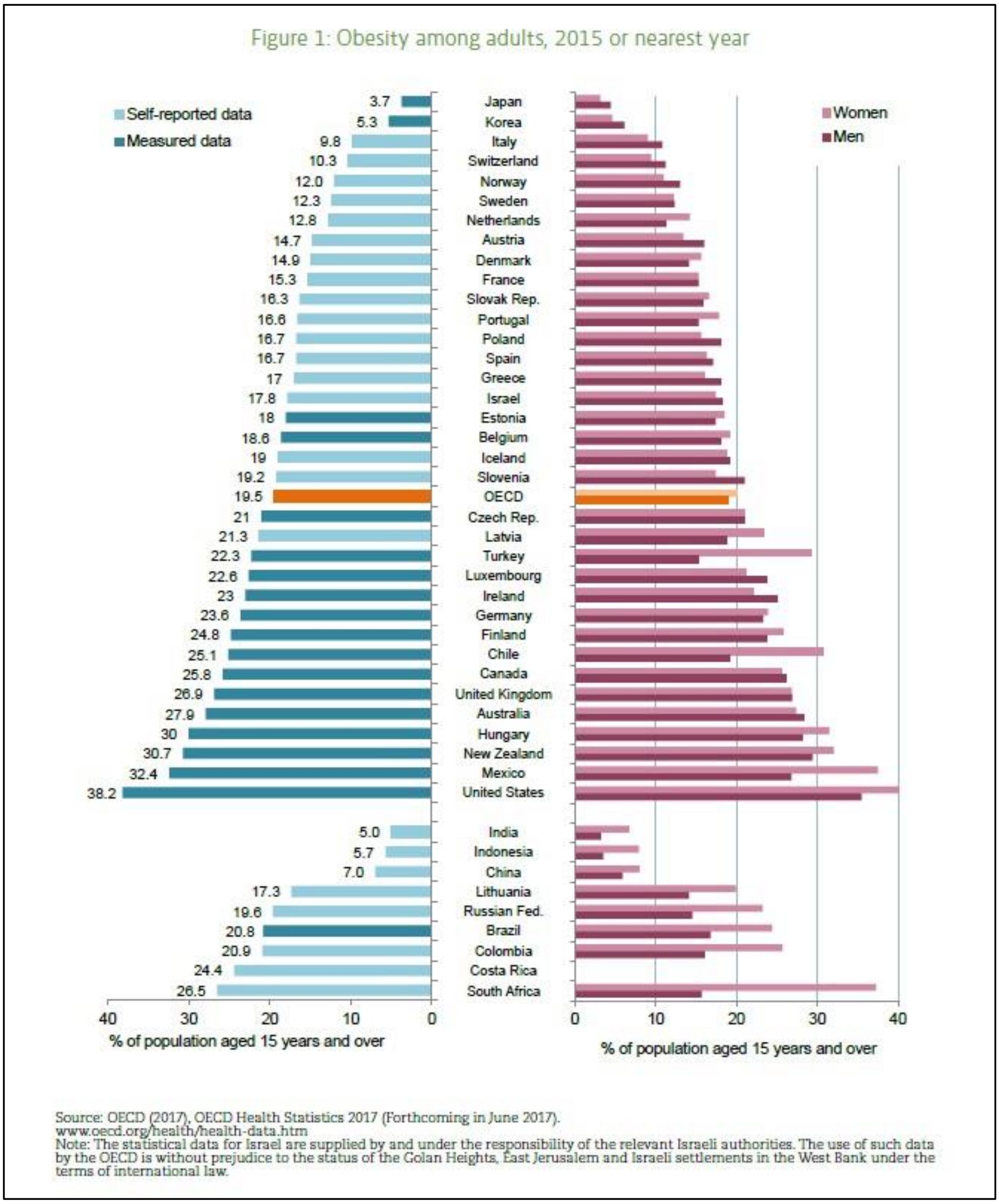
The WHO describes current rates of obesity as an epidemic [5, 14]. Additionally, in a recently published (2017) position statement, the World Obesity Federation noted that obesity is a chronic, relapsing, progressive disease process and emphasised the need for immediate action for prevention and control of this global epidemic [15, 16]. Against this background of a worldwide epidemic, obesity is a profoundly complex global public health, economic and strategic policy problem [3, 5, 8, 17, 18].

1.2.1 Prevalence of obesity and obesity-related comorbidities

The prevalence of overweight and obesity has more than doubled since 1980 [19], and the WHO has stated that worldwide obesity has nearly tripled since 1975 [10]. The Australian Institute of Health and Welfare reported that among mong Australians aged 18 and over, the prevalence of obesity alone increased over time from 19% in 1995, to 28% in 2014–15 [20].

The Organisation for Economic and Co-operative Development's (OECD) *Obesity Update 2017* stated that, in 2015, across the OECD's 35 member countries (mainly high-income countries), 19.5% of the adult population was obese [21]. Figure 1.1 highlights the rates of obesity in selected OECD countries. It also shows countries that have provided self-reported or measured data for rates of obesity.

Figure 1.1: Obesity among adults, 2015 or nearest year for selected OECD countries. Source OECD *Obesity Update 2017*.



The World Bank Group that comprises 189 member countries (including many low- and middle-income countries) has acknowledged that even while poverty and under- and malnutrition continue to affect many low- and middle-income countries, a global nutrition transition is underway [22]. The World Bank Group suggests that these changes have stimulated a rapid increase in the burden of overweight/obesity in low- and middle-income countries that was previously considered an ailment of wealthy countries. These countries are now starting to experience the double burden of overweight among both adults and children, and stunting among children [22].

Obesity-related comorbidities are complex and multifactorial [23]. It is estimated that obesity is responsible for 17.3% of coronary heart disease, 61.0% of type 2 diabetes, 24.0% of osteoarthritis, 20.8 – 35.4% of colo-rectal cancers, 26.9% of pancreatic cancer, 35.5% of gallbladder cancer, and 42.5% of kidney cancer [5, 24, 25]. Obesity has also been found to decrease health-related quality of life, particularly psychosocial health-related quality of life [26-28]. An exponential increase in the risk of adverse health outcomes is observed with increasing severity of obesity [29]. For example, it has been estimated that the risk of developing type 2 diabetes is increased 93-fold in women and 42-fold in men who are severely obese, relative to their healthy weight counter-parts [30, 31].

Notably, severe obesity is now increasing more rapidly than obesity [11].

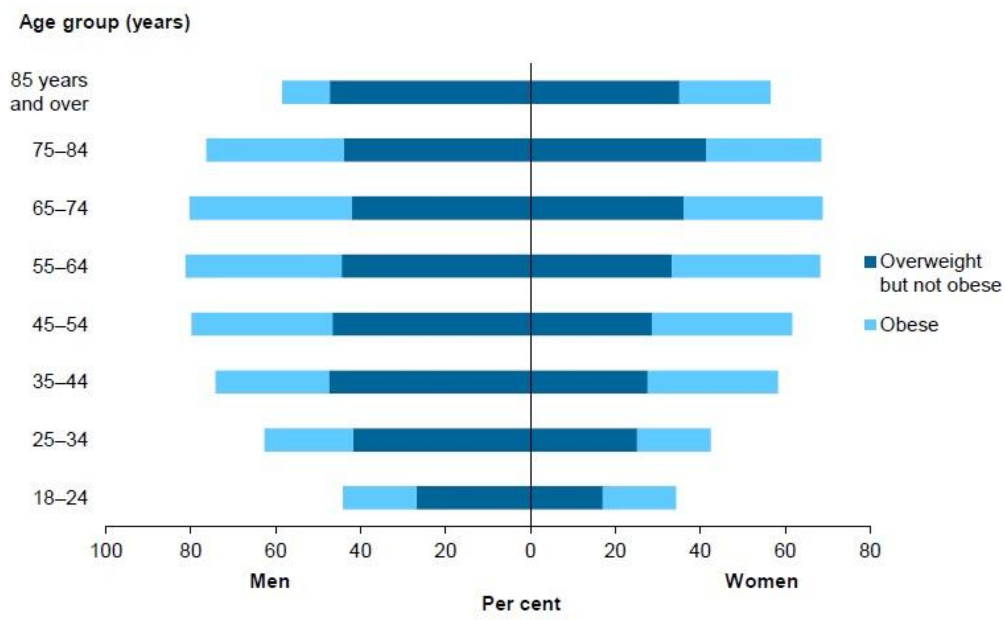
Obesity is categorised into three classes: Class 1 obesity (also labelled as obesity) is defined as BMI 30.0 – 34.9 kg/m²; Class 2 obesity (also labelled 'severe obesity' [5]) is defined as BMI 35.0 – 39.9 kg/m²; and Class 3 obesity is defined as BMI ≥ 40.0 kg/m² [19, 29]. Recent clinical literature also describes a fourth class of obesity that is categorised in the clinical literature as 'super-obesity' defined as a BMI of ≥ 50.0 kg/m² [32, 33].

A recent economic analyses that estimated the prevalence and costs of obesity and severe obesity using United States' data and informed by nonlinear regression methodology, forecast a larger increase in prevalence of severe obesity than generated from the linear trends of earlier studies [11]. The study concluded that this result is consistent with data revealing that BMI distribution among adults is becoming more right-skewed and subsequently estimated a 33% increase in obesity prevalence and a 130% increase in severe obesity prevalence over the next 2 decades to 2030 [11, 34]. If these forecasts prove accurate, this will further hinder efforts for healthcare cost containment [11]. These prevalence trends of obesity and severe obesity are also reflected globally [29, 35-37].

From Australia's perspective, a birth cohort study by the Australian Institute of Health and Welfare shows that the prevalence trends of severe obesity are increasing over time for most birth cohorts. At most adult ages (except for ages 26–29, 30–33, and 42–45), the prevalence of severe obesity was significantly higher in 2014–15 than in 1995 - those in the birth cohort born most recently at each age (measured in 2014–15) were significantly more likely to be severely obese than those born 20 years earlier (measured in 1995) [38]. The largest relative difference was for age 22–25, where 9.3% of those born in 1990 – 1993 were severely obese, compared with 3.1 % of those born in 1970–1973 [38].

For 2014 – 15, the Australian Institute of Health and Welfare recently reported that nearly two-thirds (63%) of Australian adults were overweight or obese, with Tasmania recording the highest prevalence of the Australian States and Territories. Figure 1.2 shows the prevalence of overweight and obesity in Australia by age and sex in 2014-15.

Figure 1.2: Prevalence of overweight and obesity in adults in Australia, by age and sex for 2014-15. Source: Australian Institute of Health and Welfare (2017). *Weight-loss surgery in Australia 2014-15.*



Note: The proportion for males aged 85 and over has a margin of error >10 percentage points, which should be considered when using this information.

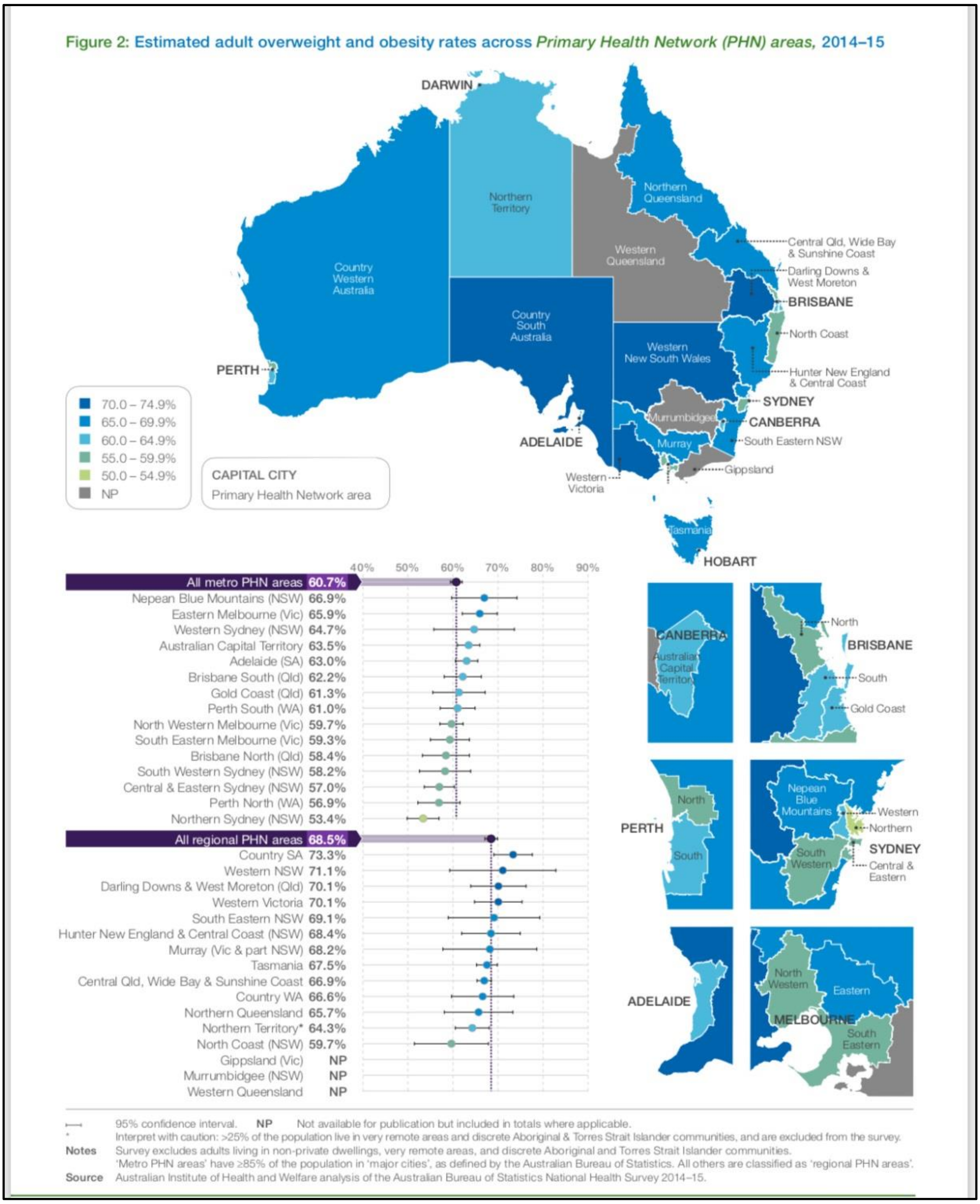
Source: AIHW analysis of ABS data (ABS 2015).

Figure 2.1: Prevalence of overweight and obesity in adults, by age and sex, 2014–15

Variation of overweight and obesity prevalence rates across Australia have been revealed in a recent analysis of the 31 Primary Health Networks for 2014-15 [39]. The analysis found there are differences in the percentage of adults who were overweight or obese between Primary Health Network areas in metropolitan and regional locations. The report stated it is important that information regarding the prevalence of overweight and obesity across Australia's Primary Health Networks be interpreted in the local context, taking into account knowledge of the local population and its needs [39].

Figure 1.3 shows that Tasmania's estimated adult overweight and obesity rate across its Primary Health Network area was 67.5%, with the range of recorded rates across the country of 53.4% in Northern Sydney to 73.3% in country South Australia [39].

Figure 1.3: Estimated overweight and obesity rates across Australia's Primary Health Network areas 2014-15. Source: Primary Health Networks. *Healthy Communities: overweight and obesity rates across Australia, 2014-15.*



A socioeconomic grading in obesity, where greater prevalence of obesity is observed in more disadvantaged groups, has been reported in most high-income countries [29, 40]. In Australia (and based on measured height and weight), Classes 1, 2 and 3 obesity prevalence increased with increasing levels of disadvantage based on both education and an area-level marker of socio-economic position [29] (Figures 1.4 and 1.5).

Figure 1.4 Prevalence of Class 1, 2 and 3 obesity by education level in Australia, 2011–12. (did not complete secondary school': 32.5%, 'completed secondary school': 22.7% and 'completed degree/diploma' 19.3%). *p<0.05. Source: Keating et al (2017). Obesity Research and Clinical Practice.

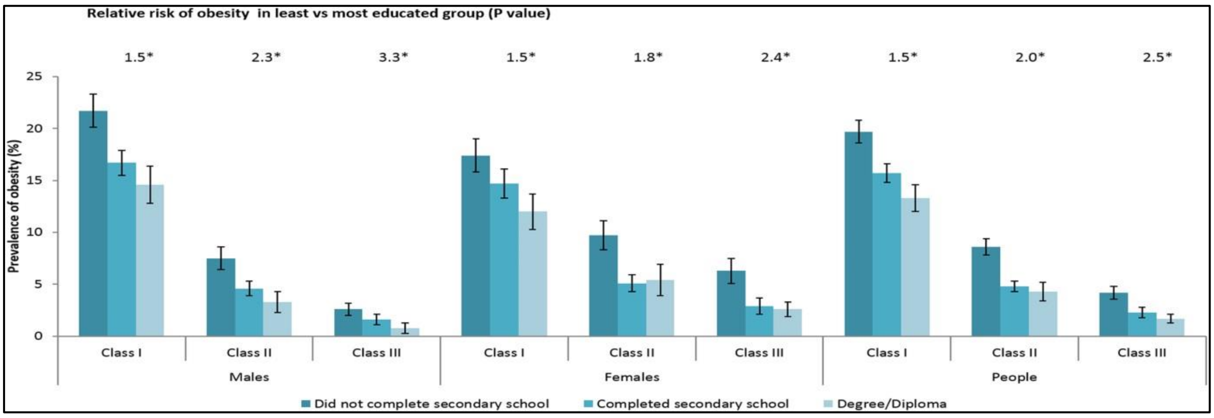
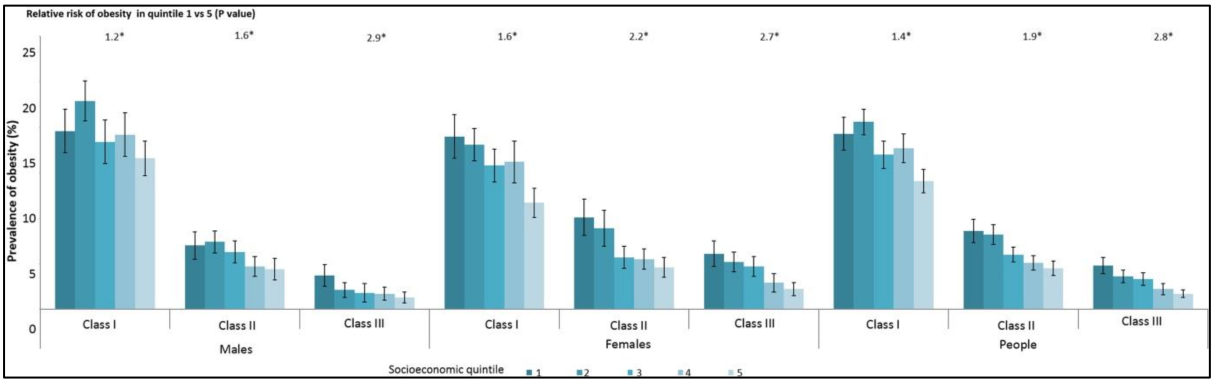


Figure 1.5 Prevalence of Class 1, 2 and 3 obesity by area-level socioeconomic status (IRSD) in Australia. 2011-12. **p*<0.05. Source: Keating et al (2017). Obesity Research and Clinical Practice.



As mentioned previously, many databases employed by economists contain only self-reports (not measured) of weight and height [5, 9, 41]. A recent study assessed the extent and characteristics of reporting error in weight, and examined its impact on regression coefficients in models of the healthcare consequences of obesity by analysing data from the United States National Health and Nutrition Examination Survey for 2003–2010 (which includes both self-reports and measurements of weight and height) [41]. The study found that reporting error in weight is non-classical: underweight respondents tend to over report, and overweight and obese respondents tend to under report their weight, with under reporting increasing in measured weight [41]. The error results in approximately one out of seven obese individuals being misclassified as non-obese. Interestingly, the study concluded that although it is a common misconception that reporting error always causes attenuation bias, comparisons of models that use self-reported and measured weight confirm that reporting error can cause upward bias in coefficient estimates [41].

In parallel with the global obesity epidemic, health spending (locally, nationally and internationally) has grown rapidly in absolute and relative terms [42, 43]. This results in the complex health economic problem of increased healthcare spending and a worldwide public health epidemic that demands even more of the scarce healthcare dollar [8]. The health economic burden of obesity is explored in detail in section 1.5 of this thesis.

Treatments for overweight and obesity include dietary therapy, exercise/behavioural interventions, weight loss medications and bariatric (also known as metabolic [44], weight-loss or obesity) surgery [45].

1.3 Bariatric (metabolic, weight-loss, obesity) surgery

Bariatric (metabolic [44, 46, 47]) surgery is considered the most efficacious intervention for severe obesity [48, 49]. It is generally recommended when non-surgical approaches have failed for adults with Class 2 obesity and obesity-related comorbidity (e.g. type 2 diabetes mellitus) or Class 3 obesity with or without obesity-related comorbidity [50]. Different surgical options are available, and they are continuously evolving, influenced by research results, specific local conditions, and the experience of the surgical staff in each location [48].

The history of bariatric surgery has been described as a science that has progressed not as a single idea by one person, but rather in small collaborative steps that take decades to accept [51]. The first recorded case of a bariatric procedure was in 1952 by a Swedish surgeon, Dr Victor Henrikson [52, 53]. He noticed that small bowel resections performed for other disease processes usually produced no change in the patient's general status however, in some cases, resulted in significant weight loss. Based on his observations, he resected 105 cm of small intestine from a 32-year-old obese female who could not complete a weight loss program. Interestingly, the patient lost only a small amount of weight but was noted to have an improved quality of life. Although this was the first reported operation for obesity, it was not adopted for treatment in other patients because of its irreversibility [51-53].

The past six decades have produced a remarkable series of new techniques and procedures for the surgical treatment of obesity and its co-morbidities [48, 49, 51, 54]. Bariatric medicine has developed as a clinical subspecialty in some countries, and others are calling for this level of subspecialisation as a treatment option for obesity [55].

1.3.1 Types of bariatric surgery, and complications and reoperations

The types of metabolic/bariatric operations are in continuous flux with different surgical options influenced by literature results, specific local conditions and the experience of surgical staff [48, 56-60]. As a rapidly evolving subspecialty of gastrointestinal surgery, bariatric surgical procedures involve gastric restriction (to augment early satiety and limit meal portions, or intestinal diversion (designed to reduce caloric absorption). Some bariatric procedures contain elements of restriction and diversion [51, 61]. Figure 1.6 provides a diagrammatic overview of the surgical procedures currently in use and others for historical context.

Figure 1.6 Overview of bariatric surgical operations. Diagrammatic representations of (A) Jejunal-ileal bypass: end-to-end jejunoileostomy with ileosigmoidostomy. (B) Biliopancreatic diversion with a duodenal switch. (C) Vertical banded gastroplasty. (D) Roux-en-Y gastric bypass. (E) Adjustable gastric band. (F) Sleeve gastrectomy. Source: Celio L., and Pories WJ (2016). A history of bariatric surgery: the maturation of a medical discipline.

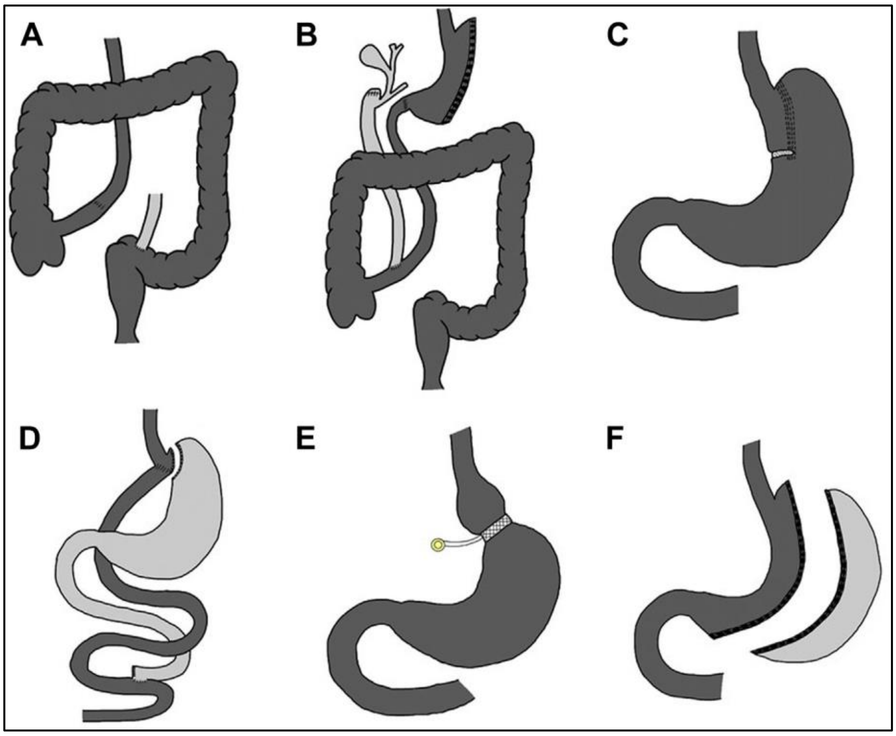
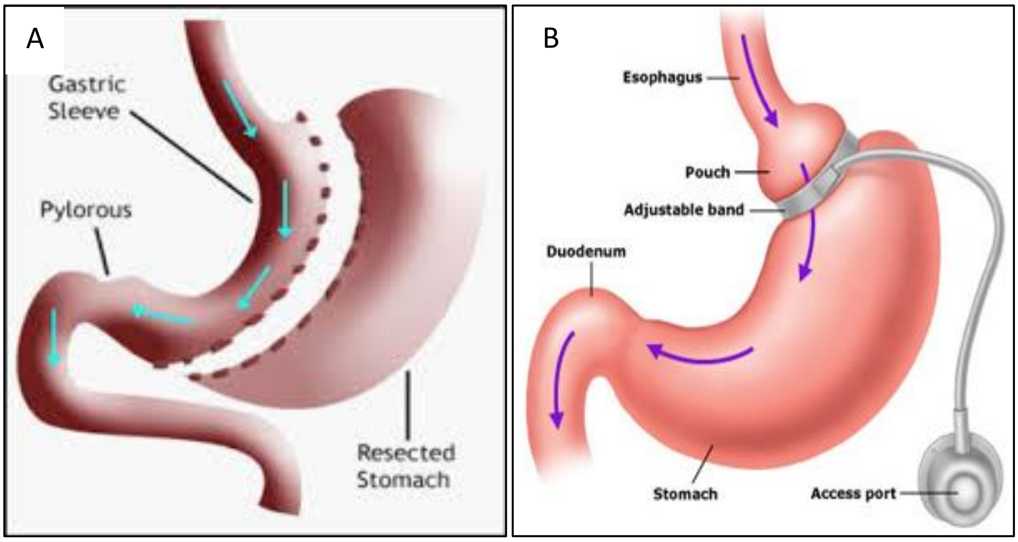


Figure 1.7 provides a diagrammatic representation of the most common procedure in Australia (sleeve gastrectomy) and the most common procedure in Tasmania (adjustable gastric band) [62]. Prevalence of bariatric surgery is detailed in section 1.4.4.

Figure 1.7 Diagrammatic representations of (A) sleeve gastrectomy (source: http://www.portlapsurgery.com.au/the-emotional-journey-to-a-sleeve-gastrectomy/) and (B) adjustable gastric band (source http://www.lapgastricband.com.au/gastric_band.html).



Sleeve gastrectomy was originally described as a staging procedure for people with super obesity to bridge them to a more definitive operation [51]. The standalone laparoscopic sleeve gastrectomy has increased in prevalence in the past decade and has many advantages over the other current operations [48, 51] Sleeve gastrectomy is: less technically demanding than the gastric bypass or biliopancreatic diversion with duodenal switch; has minimal morbidity; no implanted device; and is without marginal ulcers, dumping syndrome, internal hernias, or nutritional deficiencies [51]. Complications are mainly staple line leaks and strictures, however, the leak rate has decreased with improved surgical techniques [51]. The laparoscopic sleeve gastrectomy's favourable weight loss results, significant remission of comorbidities, and very low rates of postoperative mortality and morbidity have contributed to its rise in popularity [48, 51].

The goal of the adjustable gastric band was to develop a reversible gastric band that could be adjusted to the individual needs of the patient. A liquid-filled silastic cuff that is placed around the stomach adjacent to the cardia was used and the cuff diameter was adjusted by filling or draining fluid from a subcutaneous valve accessed by percutaneous needle puncture [51]. In 1993 the laparoscopic adjustable silicone band placement was initially described and became the most common bariatric operation in Europe and later the United States [51]. The procedure provided a less invasive and more reversible operation than a gastric bypass with similar short-term weight loss, but with long term potential risks of band slippage, erosion, and foreign body infection [51].

Some published studies have called for a reconsideration of the use and role of adjustable gastric band surgery (compared to other procedures such as sleeve gastrectomy), particularly for Medicare beneficiaries in the United States [63-65]. A recent key epidemiological study that investigated reoperation and Medicare (United States) expenditures after laparoscopic adjustable gastric band surgery found that device-related reoperation was common, costly (from a Medicare re-imbursement perspective) and varied widely across hospital referral regions. On the other hand, the invited commentary to this study suggested that no single bariatric procedure is appropriate for all patients, and that the regional variation in outcomes observed is important [64].

Complications and reoperations for each bariatric surgical procedure vary [61, 66]. A recent Cochrane systematic review concluded that assessing the risks of different bariatric procedures is still hampered by a lack of consistency and quality of evidence in the reporting of adverse outcomes and reoperation rates, and that most studies followed participants for only 1 to 2 years, therefore the long term effects of surgery remain unclear. Recently released standardised outcomes reporting guidelines for bariatric surgery [46, 47, 58] (see section 1.3.3) partially address these issues from a clinical perspective.

Accurate recording of the patient pathway will enable a true reflection of reoperations and complications (and provide relevant patient pathways for health economic analyses). Chapter 2 of this thesis finds under reporting of complications and reoperations in the health economic evaluation of bariatric surgery and this result particularly informed Chapter 8 of this thesis.

1.3.2 Eligibility for bariatric surgery: clinical guidelines

Bariatric surgery is generally recommended when non-surgical approaches have failed for adults with Class 2 obesity and obesity-related comorbidity or Class 3 obesity with or without obesity-related comorbidity [50, 67].

In Australia, the NHMRC's 2013 clinical practice guidelines for the management of overweight and obesity in adults, adolescents and children, recommend that "for adults with BMI > 40 kg/m² or adults with BMI ≥ 35 kg/m² and comorbidities that may improve with weight loss, bariatric surgery may be considered, taking into account the individual situation". The NHMRC also noted that weight loss surgery is "currently the most effective intervention for severe obesity" [62, 68].

A co-authored study external to this thesis (and a component of the NHMRC partnership project) found that within Australia, policies and guidelines on publicly-funded bariatric surgery are highly variable across Australia and at times inconsistent with national guidelines. Additionally, the study found that insufficient guidance exists regarding the prioritisation of eligible patients for bariatric surgery [69].

1.3.3 Standardised outcomes reporting guidelines for bariatric surgery

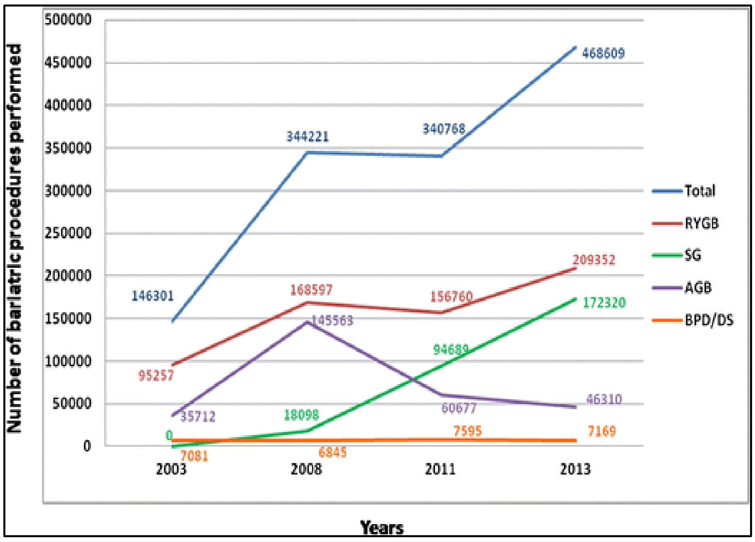
The American Society for Metabolic and Bariatric Surgeons released standardised outcomes reporting guidelines for bariatric and metabolic surgery in 2013 [46, 47]. Notably, the guidelines made no specific recommendation regarding the most appropriate health-related quality of life instrument, the recommendation being only to use a ‘validated instrument(s)’ [28].

1.3.4 Prevalence of bariatric surgery: international, national and local

The International Federation for the Surgery of Obesity and Related Diseases most recent global survey (surveys conducted in 1997, 2003, 2008, 2011 and 2013) found that the total number of bariatric procedures performed in 2013 was 468,609; 95.7% of which were carried out laparoscopically [48]. Forty-nine of the 54 bariatric surgery registered countries responded to the survey, of which 37 provided data from their national registries. USA/Canada was the region with the highest number of bariatric procedures (n=154,276). Other nations or national grouping that reported 10,000 or more bariatric procedures were Brazil (n=86,840), France (n=37,300), Argentina (n=30,378), Saudi Arabia (n=13,194), Belgium (n=12,000), Israel (n=11,452), Australia-New Zealand (n=10,467), and India (n=10,002) [48].

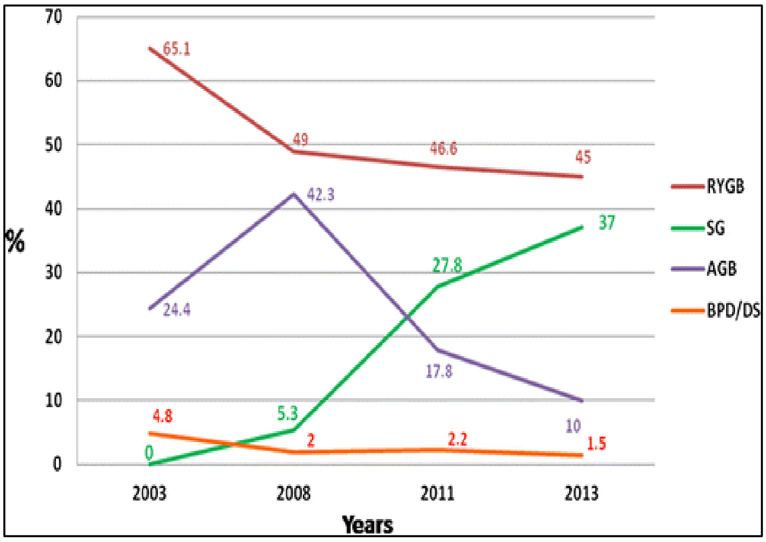
The most commonly performed procedure in the world was Roux-en-Y gastric bypass, followed by sleeve gastrectomy, and adjustable gastric banding. Figure 1.8 shows the trends in the number of bariatric surgical procedures from these global surveys over the past decade.

Figure 1.8: Trends in number of bariatric surgical procedures worldwide from 2003 to 2013. Roux-en-Y gastric bypass (RYGB), sleeve gastrectomy (SG), adjustable gastric banding (AGB), and biliopancreatic diversion with a duodenal switch (BPD/DS). Source: Angrissani, L (2015), *Bariatric surgery worldwide 2013*.



Within the total number of procedures performed, there have been marked shifts in the relative percentages of the specific bariatric procedures being done. Figure 1.9 reveals that over the past 10 years sleeve gastrectomy has increased in prevalence from 0 to 37% [48].

Figure 1.9: Trends in the percentage of procedures worldwide from 2003 to 2013. Roux-en-Y gastric bypass (RYGB), sleeve gastrectomy (SG), adjustable gastric banding (AGB), and biliopancreatic diversion with a duodenal switch (BPD/DS). Source: Angrissani, L (2015), *Bariatric surgery worldwide 2013*.



The Australian Institute of Health and Welfare reported that there were 22,713 bariatric surgery separations in Australia in 2014-15. Furthermore, most of these involved a primary procedure defined as “procedures that are typically primary or initial procedures for weight loss surgery” (not procedures that are described as adjustments, revisions, removals and other procedures) (18,036 procedures 79.4%) [62]. Laparoscopic procedures were the most common surgical technique for both separations including a primary procedure (95.0%) and those with adjustments, revisions, removals and other procedures (60.1%). The majority (88.0%, or 20,000 separations) of bariatric surgery occurred in private hospitals [62]. Notably, the most common bariatric surgical procedure is laparoscopic sleeve gastrectomy, while in Tasmania the most common procedure is laparoscopic adjustable gastric band [62]. Chapter 8 of this thesis investigated (n=105) primary bariatric surgical procedures that were conducted in Tasmanian public hospitals over an 8 year time horizon.

In Australia, recent evidence determined that the potential demand for publicly- and privately-funded bariatric surgery in Australia was 882, 441 adults aged between 18-65 years [70]. Even if only 5% of Australian adults estimated to be eligible for bariatric surgery (informed by the NHMRC eligibility criteria [50]) sought this intervention, the demand, particularly in the public health system and outside major cities, would far outstrip current capacity. Importantly, 45.8% (CI: 37.7, 54.4) of these potential bariatric surgery candidates had no private health insurance [70]. As mentioned previously, in Australia, Classes 1, 2 and 3 obesity prevalence increased with increasing levels of disadvantage [29]

Constrained public sector budgets contribute to the incapacity of the Australian public health system to address the problems of severe obesity increasing more rapidly than overall obesity [71]. This problem is reflected internationally [35, 36, 72].

1.4 Introduction to Health Economics

1.4.1 Neoclassical economic theory and some departures from the 'parent discipline'

Whilst a full exploration of economic and health economic concepts is beyond the scope of this chapter, a brief discussion of key concepts provides background to the conceptual and methodological approaches employed in this thesis. Key neoclassical economic concepts are outlined, followed by health economics adoption of these concepts from the 'parent discipline' [73] and departures from these fundamental concepts enabling the emergence of the highly specialised discipline of health economics.

Economics is a discipline concerned with *scarcity and choice* - the existence of limited resources and unlimited human wants. We are forced to make choices among competing objectives – an inescapable result of scarcity [1]. Within this framework of unlimited wants and finite resources, positive economics is concerned with 'what is', whereas normative economics embodies subjective feelings about 'what ought to be' [74].

Neoclassic economic theory states that a resource is scarce whenever it has a non-zero opportunity cost [42]. Opportunity cost recognises that everything and everyone has alternatives – the cost of any decision or action is measured in terms of the value placed on the opportunity foregone [1, 42]. Neoclassical economic theory also assumes that human behaviour reflects 'rational self-interest': individuals look for and pursue opportunities to increase their utility (their satisfaction and happiness) [74]. A perfectly competitive market exists if all the following conditions can be satisfied: many buyers and many sellers, perfect information, free entry and exit, and a homogenous product [42]. Neoclassical theory states that perfectly competitive markets will achieve both allocative and productive efficiency; the most desired products are produced in the least costly way [42, 74].

The concept of efficiency measures how well resources are being used to promote social welfare [1]. The 'welfarist' view is that Pareto efficiency is an allocation of resources such that it is not possible to reallocate any of them without imposing uncompensated losses of utility on some individual [75]. Potential Pareto efficiency is another important concept of efficiency and the idea is that if gainers from a change could compensate losers and still gain then there is an increase in social welfare (even if the compensation is not actually paid) [76]. Additionally, if potential losers can offer gainers an equivalent gain sufficient for them to forgo the proposed change and still be better off than with the change, then the change will not enhance welfare (even if the equivalent is not actually paid) [76]. Importantly, it has been proposed that "these 'contortions' are gone through in order to avoid having to face up to the reality that a dollar of gain may not be of the same value to each person or, even if it were, that it should be so treated in the social welfare function" [76]. Compensation tests are a way of trying to identify Pareto improvements or potential Pareto improvements [76].

Extra-welfarism is a different idea of efficiency developed within the separate discipline of health economics [75, 77]. With extra-welfarism (rather than general utility or welfare) as the framework, the maximand may be whatever the analyst or policy maker selects as appropriate, and in health policy, health or health gain are common objectives [75, 76, 78]. Recent literature has suggested that the definition of extra-welfarism has been unclear and confused over the years [73]. Extra-welfarism has been more clearly defined recently in the following terms: '(i) it permits the use of outcomes other than utility; (ii) it permits the use of sources of valuation other than the affected individuals; (iii) it permits the weighting of outcomes (whether utility or other) according to principles that need not be preference-based and (iv) it permits interpersonal comparisons of well-being in a variety of dimensions, thus enabling movement beyond Paretian economics [73, 78].

A recent study contended that whilst professing to have increased the evaluative space from a concern with utility alone, in practice extra-welfarism appeared to have altered the evaluative space from utility to a much narrower domain: that of the health of patients [73]. Additionally, extra-welfarism cannot draw on the equity and efficiency divide - instead it has been suggested that it draws much more on classical utilitarianism and that is a specific ethical position that health economists need to be more aware that they are supporting [73].

While efficiency is one ethical imperative in the design and operation of health services and other determinants of health, equity is another [76]. It has been suggested that equity is not necessarily to be identified with equality or egalitarianism, but relates in general to ethical judgments about the fairness of income and wealth distributions, cost and benefit distributions, access to health services, exposure to health- threatening hazards and so on [76]. Although not the same as ‘equality’, equity frequently involves considering the equality of something (such as opportunity, health, access). Horizontal equity refers to the fairness (or equality) in the treatment of apparent equals (such as persons with the same income). Vertical equity refers to fairness in the treatment of apparent unequals (such as persons with different incomes) and, by contrast, concerns fair inequalities [76].

The World Health Organization proposes that *‘health equity’ implies that ideally everyone should have a fair opportunity to attain their full health potential and that no one should be disadvantaged from achieving this potential’*. Furthermore the World Health Organization’s Director-General (Dr Tedros) says that *‘I envision a world in which everyone can live healthy, productive lives, regardless of who they are or where they live’* [79]

Healthcare markets exhibit special features that are departures from the purely competitive market and these departures include: ethical and equity considerations (ethical questions inevitably intervene in markets where decisions involve quality of life, and literally life and death); asymmetry of information where healthcare buyers typically have less information than physicians; positive externalities where the medical care market often generates positive spillovers; and third-party payments (insurance) [42, 74]. The next section provides further detail regarding some of the differentiating characteristics of health economics as a separate discipline from its 'parent discipline' of economics.

1.4.2 The emergence of health economics as a specialist discipline

Health economics has been described as the application of economic theory (generally neoclassical microeconomic theory) to phenomena and problems associated with health and healthcare [76]. On the other hand, health economics and the work of health economists have been described as much broader than adopting the Paretian approach [75]. It has been suggested that although most health economists use the familiar theoretical tools of neoclassical economics, that they are by no means (and possibly not even a majority) committed to the welfarist (specifically Paretian) approach usually adopted by mainstream economists when addressing normative issues [75]. This departure from mainstream neoclassical theory by health economists turns out to have been the territory in which some of the most innovative ideas of health economics have been generated [75].

Kenneth Arrow is recognised as the father of the highly specialised discipline of health economics. In his ground-breaking seminal paper titled *Uncertainty and Welfare Economics of Medical Care* Arrow stressed the prevalence of uncertainty in healthcare, both on the demand side and the supply side [42]. Healthcare markets display a number of significant and special characteristics that differentiate them from a perfectly competitive market, including pervasive uncertainty, unavoidable information asymmetries and the need for principal-agent relationships [80].

For example, the patient-physician relationship is a classic example of the principal-agent relationship in health economics [81]. Arrow's seminal paper explored and described the concept of product uncertainty and consumer information in the 'medical-care market' [82]. Notably, he outlined the concept of asymmetry of information by introducing the following concepts:

> *"Because medical knowledge is so complicated, the information possessed by the physician as to the consequences and possibilities of treatment is necessarily very much greater than that of the patient, or at least so it is believed by both parties. Further, both parties are aware of this informational inequality, and their relation is coloured by this knowledge."*

As suggested above, the highly specialised discipline of health economics has developed and expanded in scope since Arrow's (1963) seminal paper, especially since the rise of health economic evaluation in the 1990s [82, 83]. For example, behavioural economics [80, 84], capability and sufficient capability approaches [85], extra-welfarism versus welfarism [77, 78], economics of risky health behaviours (including obesity, time-inconsistent preferences and bounded rationality [86]) and neuroeconomics [86-88] are examples of the expansion and rapidly evolving discipline of health economics.

Nevertheless, the concepts and tools of health economic evaluation are fundamental to many key health economic resource allocation decisions worldwide [83]. Over the past 20 years two factors have led to an increased prominence of economic evaluation within health care decision-making nationally and internationally [83]. First, increasing pressures on health care budgets have led to a shift in focus from merely assessing clinical effectiveness, to one on assessing both clinical effectiveness and cost-effectiveness [83]. Secondly, decision-making processes have emerged in several jurisdictions that enable the results of economic evaluations to be used as an integral part of funding, reimbursement, or coverage, decisions [83].

1.4.3 Health economic evaluation

Economic evaluation is defined as *'the comparative analysis of alternative courses of action in terms of both their costs and consequences'* [83]. Economic evaluation of health technologies seeks to promote the efficient allocation of health care [89]. Economic evaluation can be classified as partial (e.g. a cost-outcome study or cost analyses) or full economic evaluation (e.g. cost-benefit analysis, cost-effectiveness analysis, or cost-utility analysis) [83].

The basic tasks of any economic evaluation are to identify, measure, value and compare the costs and consequences of the alternatives being considered [83, 90]. Costs should be estimated with the theoretical price of the resource used as its opportunity cost that is the value of its foregone benefits because the resource is not available for the resource's next best alternative use) [83, 90]. However, there are pragmatic approaches for adjusting prices that are beyond the scope of discussion in this section [83, 90]. Costing plays a vital role in Australia's Activity Based Funding model (section 1.4.5 and Chapter 8 of this thesis).

In regard to full economic evaluation, cost-benefit analysis adopts a 'welfarist' philosophy and consequences are measured in monetary units [83, 91]. Cost-benefit analysis rests on the premise that a project, policy or intervention will improve social welfare if the benefits associated with it exceed its costs [42]. Cost benefit analysis usually requires the calculation of present values using a social discount rate and the usual decision rule in cost-benefit analysis is for the benefit-cost ratio (B / C) to exceed unity or for (B – C) > 0 [75].

Cost-effectiveness analysis adopts an 'extra-welfarist' philosophy [78] and measures consequences in natural units, such as life-years gained, disability days avoided, or cases detected. In regard to bariatric surgery the measured consequences could also include type 2 diabetic free year or additional case of T2DM remitted, or BMI unit decrements and so on. In a variant of cost-effectiveness analysis, called cost-utility analysis, consequences are measured in terms of preference-based measures of health namely quality-adjusted life years (QALYs) or disability-adjusted life years (DALYs) [83, 91]. Further detail regarding QALYs is outlined in section 1.4.4.

Figure 1.10 describes the distinguishing characteristics of partial and full healthcare economic evaluations [83].

Figure 1.10 Distinguishing characteristics of healthcare economic evaluations. Source: Drummond et al (2005 and 2015), Methods for the Economic Evaluation of Health Care Programs.

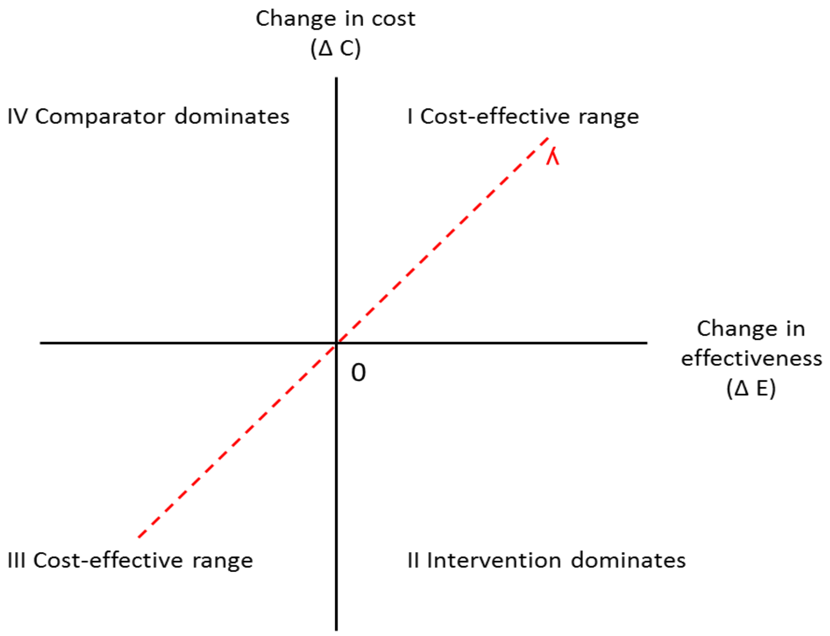
Are both costs (inputs) and consequences (outputs) of the alternatives examined

Is there a compari-son of two or more alternat-ives

<table>
<tr><td rowspan="3">No</td><td colspan="2">No</td><td rowspan="2">Yes</td></tr>
<tr><td>Examines only consequences</td><td>Examines only costs</td></tr>
<tr><td>1A Partial Evaluation
Outcome description</td><td>1B Partial evaluation
Cost description</td><td>2 Partial evaluation
Cost-outcome description</td></tr>
<tr><td>Yes</td><td>3A Partial evaluation
Efficacy of effectiveness evaluation</td><td>3B Partial evaluation
Cost analysis</td><td>4 Full economic evaluation
What should count?
How should it be measured?
How should it be valued?</td></tr>
</table>

The incremental cost-effectiveness ratio (or the incremental cost-utility ratio for cost-utilty analysis) is defined as the differences between the costs of two alternatives and the difference between their effectiveness or outcomes. The algorithm for the incremental cost-effectiveness ratio is the cost of the intervention minus the cost of the comparator divided by the effectiveness of the intervention minus the effectiveness of the comparator. The incremental cost-effectiveness ratio can then be mapped onto the cost effectiveness plane (a diagrammatic way of comparing two technologies - see Figure 1.11 [76]) to compare the technologies.

Figure 1.11: The cost-effectiveness plane is a diagrammatic way of comparing two technologies. A four quadrant diagram of cost difference plotted against effect difference yields quadrant I (intervention is more effective and more costly than the comparator), quadrant II (intervention is more effective and less costly than the comparator), quadrant III (intervention is less effective and less costly than the comparator), and quadrant IV (comparator dominates the intervention). Quadrants I and III represents cases where the cost-effectiveness of the alternatives depends on the size of the incremental cost-effectiveness ratio and on whether the ΔE is positive or negative. The dashed red line ʎ represents the willingness-to-pay threshold. All points below the willingness to pay threshold are in the region of acceptability. Source: Adopted from Culyer (2010), Dictionary of Health Economics.



The choice of cost-effectiveness threshold (or the willingness-to-pay threshold) is crucial in determining the value of healthcare interventions – international willingness to pay thresholds vary [61, 92]. For example, in Australia, the Pharmaceutical Benefits Advisory Committee was unlikely to recommend a drug for listing if the incremental cost-effectiveness ratio exceeded $76,000 (Australian dollars) [26, 93]. Similarly, the National Institute for Health and Care Excellence (United Kingdom) has never identified an incremental cost-effectiveness ratio above which interventions should not be recommended and below which they should. However interventions with an incremental cost-effectiveness ratio of less than ₤20,000 per QALY gained are considered to be cost-effective. As the incremental cost-effectiveness ratio of an intervention increases in the ₤20,000 to ₤30,000 range, an advisory bodies judgment about its acceptability as an effective use of National Health Service resources should make reference to relevant factors outlined by the Institute [61, 94]. There is an ongoing debate in health economics about setting thresholds (e.g. using the World Health Organization-recommended cost-effectiveness thresholds of 1 to 3 times GDP per capita versus cost-effectiveness thresholds reflecting opportunity costs) [95]. A recent study has suggested that rather than settling on a single threshold, it would be preferable to use multiple thresholds, ideally ones based on the available resources for the relevant decision maker and possible alternative uses of those resources. For example, decision makers in resource-poor settings would have a lower willingness to pay threshold [61, 95].

The perspective (or viewpoint) of the economic evaluation is important because a program or intervention that looks unattractive from one perspective may look significantly better when other perspectives are considered [83]. The perspective of a health economic evaluation will reflect the perspective of the individual, the payer or society [83].

Although economic evaluation can be applied to all health technologies, including drugs, devices, procedures, and systems of organisation of health care, in the main the formal requirement for assessment of cost-effectiveness has been applied to pharmaceuticals. This formal requirement was first introduced in Australia in 1993 and the policy has been adopted in numerous countries (e.g. half the countries of the EU, Canada, NZ, and several payers of the United States and some countries in Latin America and Africa) [83]. Government policy in the United States is that cost/QALY thresholds have been legislated against [95].

Some jurisdictions have requested economic evaluations for technologies other than drugs, including the United Kingdom, where the National Institute for Health and Care Excellence assesses the clinical and cost-effectiveness of a wide range of technologies, including public health interventions, before issuing guidance for their use in the National Health Service. Economic evaluations have been much more prominent in jurisdictions with single-payer systems, most notably Australasia, Canada, the Scandinavian countries, and the United Kingdom [83].

There is tension between the academic rigour of health economics and the realities of policy making [75, 96]. Recent literature discussed the policy use of economic evaluation in healthcare: evidence from economic evaluation in healthcare decision making is used if the evidence is accessible and acceptable [96]. Interestingly, there has also been a call to adopt the capability and sufficient capability approaches in economic evaluation [73].

Furthermore, there has also been a call for the use of qualitative research methods to improve practice in health economic evaluation - Chapters 6 and 7 of this thesis make a novel contribution to the literature regarding qualitative research. The broader discipline of health economics is repeatedly scrutinised for its relevance and translation into healthcare policy making [97]. As a professional community that strives to convince the decision maker about the optimal allocation of the scarce healthcare dollar at the margin, our research will only be relevant if decision makers trust that we have considered all of the costs and benefits that are in fact relevant (and a priority) to the recipients of the healthcare dollar.

1.4.4 Health-related quality of life

The International Society for Quality of Life Research states that a number of definitions of health-related quality of life exist and that there is broad agreement that health-related quality of life is a functional effect of a medical condition and/or its consequent therapy upon a patient [98]. Health-related quality of life is thus subjective and multidimensional, encompassing physical and occupational function, psychological state, social interaction and somatic sensation [98].

It is beyond the scope of the thesis to explore the published literature regarding the assumption that a person is the best judge of the value of worth of their own lives [99]. Nevertheless, when researchers measure a person's overall quality of life in terms of his or her self-reported happiness or satisfaction, they are most likely assuming that people are the best judges of the value or worth of their own lives and that as their reported levels of happiness or satisfaction increase or decrease, the quality of their lives (its value or worth) is increasing or decreasing [99].

Measures of happiness and socialising activities are important measures of overall quality of life and broader health-related quality of life research suggests that self-perceived good health is not equivalent to perceived quality of life: that is 'good health is not the same as good life' [100]. In turn, psychosocial health status has been increasingly identified as a crucial health-related quality of life outcome measure for the morbidly obese population who then receive bariatric surgery [28]. Additionally, long-term waitlisted bariatric surgery patients realise significant psychosocial health-related quality of life gains when ultimately treated [26, 27].

Numerous instruments have been created which produce indices of health-related quality of life including generic (e.g. Short Form (SF)-36, EQ-5D-5L and Assessment Quality of Life (AQoL)-8D) and non-generic instruments (e.g. BOSS (Bariatric and Obesity Specific Survey), or IWQoL-lite) A subset of the generic instruments is multi-attribute utility instruments (e.g. EQ-5D-5L and AQoL-8D) that create indices of health state utility valuations [101]. A health state utility valuation is an important health economic metric that measures the strength of preference for a particular health state and a health state utility valuation is represented as a number on a scale where ‘1.0’ represents the best possible health state and ‘0.0’ represents death. In principle, values less than 0.0 are possible when a health state is worse than death [27, 102]. Importantly health state utility valuations are key health economic metrics that are an input measure to QALYs in cost-utility analysis [83]. A QALY provides a year of future life expectancy adjusted for the expected quality of life during that time: in the formation of the QALY multiple effects of health care provision are essentially reduced to a single value and this single score is then used to weight years of future life expectancy to give years of quality-adjusted future life expectancy. QALYs have been aligned with the extra-welfarism perspective in the United Kingdom [78].

Multi-attribute utility instruments are a health-related quality of life assessment tool designed to rapidly and conveniently assess and capture an individual’s health state utility values through application of pre-established formulae/weights to the array of self-reported responses obtained on the multi-attribute utility instrument’s questionnaire. A multi-attribute utility instrument is developed and defined with particular characteristics including: the number of questionnaire items, the depth and breadth of the descriptive/classification system, the number of health states described, the number of individual and super dimensions (if there are super dimensions) and the algorithmic range [27, 103].

The EQ-5D-3L and EQ-5D-5L multi-attribute utility instruments dominate clinical and economic evaluation studies, including the obesity and bariatric surgery published studies [61, 104]. The standard format of the EQ-5D descriptive health classifier system consists of five dimensions of health, each with three levels of problems for the EQ-5D-3L (243 health states) or the more recently developed 5-level EQ-5D-5L that expands the range of responses to each dimension from three to five levels (3,125 health states) [105]. Four out of the five EQ-5D-5L domains of health focus on physical health only [106].

1.4.5 Australia's Activity Based Funding model

In August 2011 the Council of Australian Governments ratified the National Health Reform Agreement that informed the establishment of Australia's Independent Hospital Pricing Authority (IHPA). IHPA plays a pivotal role in Activity Based Funding model through key functions outlined in section 3B of the National Health Reform Agreement [107].

IHPA states that Activity Based Funding is a way of funding hospitals whereby they get paid for the number and mix of patients they treat. If a hospital treats more patients, it receives more funding. Additionally, because some patients are more complicated to treat than others, Activity Based Funding also takes this factor into account [108].

Within the ABF funding model our Tasmanian State Government project partner focuses on costs at the patient level. The DHHS states that a consistent approach to identifying how individual patient costs are constructed can help organisations understand where variations arise within a patient pathway, for example, in theatres, wards or diagnostics [109]. The DHHS's development of patient level costs builds costs from the bottom-up, identifying where possible the resources used in treating individual patients – for example, prosthetic devices (such as laparoscopic adjustable gastric band appliance), the intensity of nursing resources and indirect or overhead costs such as the costs of the payroll or finance team through appropriate allocation and apportionment methods [109].

Every year within the Tasmanian public healthcare setting, an annual State hospital costing study that use bottom-up costings are undertaken that match patient activity and usage data from various hospital information systems with costs from the general ledgers [109]. This work aims to cost all hospital activity covering all products and this essential work underpins the Activity Based Funding model requirements laid out by the National Health Reform Agreement signed by the Australian States and Territories and the Commonwealth [109].

1.5 The health economic burden of obesity

1.5.1 The health economic burden of obesity worldwide

In contrast to the research on the economic causes of obesity that is often characterised by conflicting results, the evidence on the economic consequences of obesity is relatively consistent: obesity worsens labour market outcomes (such as lower wages and lower probability of employment) and raises medical care costs [5]. Moreover, medical care costs do not rise significantly with BMI until the severe and morbid obesity range (Class 2 and Class 3 obesity) [5].

The economic burden of the obesity epidemic and its associated comorbidities places undue stress on healthcare systems [110]. A recent systematic review regarding the direct costs of obesity worldwide found that obese individuals have medical costs that were approximately 30% greater than their normal weight peers [110]. Nevertheless, this review stated that cost-of-illness analyses for most diseases are commonplace for most diseases, but the complexities for obesity and its constantly expanding list of comorbidities makes obesity’s evaluation challenging. For example, in a recent review of decades of Canadian obesity research, only 1%

pertained to costs and healthcare utilisation, and Canada does not seem to be unique in this phenomenon [110].

The economic burden of obesity also extends well beyond the healthcare sector into societal domains including work productivity [7, 13, 111-113], and personal and family impacts arising from discrimination and stigmatisation of the overweight and obese both individually and collectively, poorer relationships and social engagement [6, 114].

A recent study that estimated the savings in medical expenditures associated with reductions in BMI among United States adults with obesity found that the relationship between medical care costs over BMI is J-shaped: costs rise exponentially in the range of Class 2 and Class 3 obesity (BMI $\geq$35 kg/m^2) [23]. The study found that the heavier the obese individual, the greater the reduction in medical care costs associated with a given percent reduction in BMI and that medical care expenditures are higher, and rise more with BMI, among individuals with diabetes than among those without diabetes [23].

1.5.2 Australia's healthcare system and the health economic burden of obesity in Australia

The Australian healthcare system is characterised by a complex and fragmented set of arrangements between the public (two tiers of government) and private sectors [115]. The national government (the Commonwealth) holds the major revenue-raising powers, so the States and Territories (six States and two Territories) rely on financial transfers to provide services. The States operate public hospitals (which account for about two thirds of all hospitalisations and provide emergency department visits without charge), though funding them is a joint responsibility of both levels of government. The Commonwealth has responsibility for paying benefits through Medicare (for out-of-hospital medical care and in-hospital private medical services) and for the Pharmaceutical Benefits Scheme (covering most prescribed drugs), however, funding arrangements for other services often involve both levels of government [115]. The National Health Reform Agreement was signed by all States and the Commonwealth in 2011. It established a new basis for the Commonwealth's contribution to public hospital funding, based on organisations' case-mix and known as Activity Based Funding [104, 105].

Total spending on health in Australia was $170.4 billion in 2015-16 [43]. The share of the economy (Gross Domestic Product (GDP)) represented by health was 10.3% [43]. Of this total government health expenditure was $114.6 billion, or approximately two-thirds (67%) of all health expenditure [43]. Government expenditure on public hospital services was $46.9 billion (40.9% of total government expenditure) in 2015-16 [43]. State and Territory expenditure accounted for 52.2% of all sources of expenditure on public hospital services in 2015-16 [43].

Non-government sources (individuals, private health insurance funds, and other non-government sources) spent $55.8 billion on health in 2015-16 (32.7% of total health spending) [43]. Expenditure by individuals accounted for 52.7% of non-government expenditure and represented 17.3% of total health expenditure [43]. Forty seven percent of Australians are privately insured, and there is 100% public coverage through Medicare [115].

The most recent estimate contained in the published literature of the total annual direct cost of overweight and obesity in Australia in 2005 was estimated to be 21 billion Australian dollars and this estimate was substantially higher than previous estimates [116]. The authors concluded that there are financial incentives for individuals, governments and societies to address the obesity epidemic in Australia [116]. Over a decade later, the prevalence of severe obesity and the associated co-morbidity loads are increasing.

1.5.3 Some health economic policy challenges regarding obesity and bariatric surgery

Against a multifactorial background of a worldwide epidemic, obesity is a profoundly complex global public health, economic and strategic policy problem [4, 2, 7, 12, 13]. It has been suggested that there is no magic bullet that will solve the problem of obesity, but numerous policies with modest beneficial effects, if enacted jointly, could result in meaningful change [117].

Examples of market failures relevant to obesity include imperfect information, negative externalities, and irrational behaviour [86]. Imperfect information leads to the health economic problem of asymmetry of information between the supplier (physician) and consumer (patient) [82]. Most studies regarding asymmetry of information investigate the physician's superior knowledge (supplier-induced demand), rather than the consumer's knowledge (demand-induced supply) [81].

In regard to irrational behaviour, the growing field that investigates the economics of risky behaviours reveal that time-inconsistent preferences can lead to excess weight. Such preferences are characterised by someone expressing the desire for a healthier lifestyle, but consistently succumbing to immediate gratification [84]. Suggestive evidence of time-inconsistent preferences is that the majority of obese men, and more than two-thirds of obese women, report having attempted to lose weight in the past year [86].

One way to solve this problem of time-inconsistent preferences is to offer obese individuals pre-commitment devices - the most dramatic pre-commitment device is bariatric surgery, which allows a person to pre-commit to eating less in the future by having the size of their stomach surgically reduced and in other ways decreasing the pleasure associated with eating [117].

1.6 Qualitative research methods in health economics – improving practice?

Health economics is repeatedly scrutinised for its relevance and translation into healthcare policy making [97]. Over the past decade, there has been a call for health economists to effectively integrate combinations of qualitative and quantitative methods into their research toolkit to enrich their research methodologies and therefore improve their practice in health economic study design, data gathering and analyses, reporting, and ultimately research translation [118-123]. Additionally, health policy development, research, and management could benefit from more in-depth, textured descriptions of what actually happens in practice settings, healthcare markets, and patients' lives [124, 125]. Nevertheless, recent evidence has found that only 9% of published health economic research adopts qualitative research methods [122, 125].

My systematic review established that the health economic reporting of bariatric surgery is dominated by quantitative methods that adopt a narrow payer perspective [61]. Additionally, the EQ-5D suite of instruments dominates the cost-utility studies regarding bariatric surgery - the EQ-5D focuses on physical health rather than psychosocial health [61]. Qualitative research methods could improve our practice in health economic evaluation of bariatric surgery by eliciting costs and consequences that would not be captured with traditional quantitative methods.

There is also a call for health economists to implement mixed-methods policy-relevant research that is embedded in and derived from real-world policy settings [119, 122, 126]. Mixed-methods policy-relevant and translatable research can be successfully generated through research partnerships between knowledge-users (e.g. government) and academic researchers [127].

1.7 Evidence gaps: health economic reporting of bariatric surgery

Chapter 2 of this thesis contains a comprehensive systematic review of the health economic evaluation of bariatric surgery from 1995 to 2015 that included 77 partial and full economic evaluations of bariatric surgery [61]. The review found that the health economic reporting of bariatric surgery is characterised by heterogeneous approaches of inconsistent quality and identified key gaps and common themes in the reporting of bariatric surgery [61].

Some of the key gaps identified by this research included: only a limited spectrum of direct medical costs was considered in the majority of studies including a lack of consideration of the costs of many important longer term post-operative events like reoperations, complications and body contouring surgery; a paucity of information on indirect costs such as out-of-pocket expenses to patients and their families, work productivity gains and/or losses, and the impact of being waitlisted for bariatric surgery, and the rapid increase in severe obesity (compared to overall obesity) where demand for bariatric surgery was continually exceeding the increase in supply. The systematic review also found that bariatric surgery was cost-effective/cost-saving for severely obese with type 2 diabetes mellitus.

1.8 Key research aims of this thesis

As a health economist within the National Health and Medical Research Council partnership project team, the principal aims of my PhD research were to:

- Provide critical baseline analyses of the evidence gaps and key themes regarding the health economic reporting of bariatric surgery, locally, nationally and internationally;

- Address key evidence gaps regarding the capture and measurement of the physical and psychosocial domains of health-related quality of life of people with obesity waiting for, or who have received bariatric surgery;
- Use qualitative research methods to investigate bariatric surgery patients' experiences to identify and prioritise health economic costs and consequences of bariatric surgery that are typically excluded from existing studies or not given appropriate priority; and
- In collaboration with our NHMRC health partner, estimate the health service resource use and direct costs for patients (i) waiting for bariatric surgery, (ii) the index of surgery, and (iii) for up to three years post-surgery.

1.9 Summary of the methods and structure of this thesis

This thesis has provided much needed information for health economists and health policy decision makers regarding the key health economic evidence gaps for obesity and bariatric surgery internationally, nationally and in Tasmania.

To achieve the research objectives of my PhD project, this thesis adopted a mixed-methods approach of both quantitative and qualitative research methods, within real-world policy settings, consistent with a call for health economists to implement mixed-methods policy-relevant research that is embedded in and derived from real-world policy settings [21-23].

First, validated guidelines and methodologies were followed in the systematic selection and narrative synthesis and analyses of the published literature regarding the health economic evaluation of bariatric surgery. The findings of this comprehensive systematic review informed the methods of the remainder of this thesis.

Second, the vastly different EQ-5D-5L and AQoL-8D multi-attribute utility instruments were systematically selected to investigate health state utility in two recruited cohorts of bariatric surgery patients. Patients who had received bariatric surgery many years previously in the private healthcare system (cross-sectional study) and patients who had waited for bariatric surgery for many years and who were then operated on as part of a government policy decision to reduce waiting lists (longitudinal study) were studied.

Third, qualitative research methods were used to investigate bariatric surgery patients' experiences to identify and prioritise health economic impacts of bariatric surgery that are typically excluded from existing studies. Over the past decade, there has been a call for health economists to effectively integrate combinations of qualitative and quantitative methods in their research toolkit to enrich their research methodologies and therefore improve their practice in health economics study design, data gathering and analyses, reporting, and ultimately research translation.

Ten focus groups (n=49 participants) were conducted, transcribed verbatim and analysed thematically with the assistance of software. Themes were identified inductively through a dialogue between the qualitative data and pre-existing economic theory.

Fourth, a strategic research alliance with our NHMRC project partner, the State Government of Tasmania's Department of Health and Human Services was self-assembled with heterogeneous human capital. Quantitative research methods were adopted to construct and analyse a real-world resource use and cost database regarding resource use and costs to the Tasmanian public hospital system before and after bariatric surgery (n=105 patients; n=779 episodes-of-care).

This thesis is structured in the following way.

Chapter 1 has presented an overview of the obesity epidemic, bariatric surgery as a treatment option for obesity, and health economics as a separate and important discipline of economic inquiry. This chapter also presents the methods, key research objectives and structure of this thesis.

Chapter 2 provides a comprehensive systematic review informed by broad selection criteria of the health economic evaluation of bariatric surgery from 1995 to 2015. A quality appraisal of the included studies against the Consolidate Health Economic Evaluation Reporting Standards checklist is also conducted. The findings of this study informed many aspects of the remainder of this thesis, and some of the future directions for research. Appendix 2A contains the published article [61].

Chapter 3 presents the thesis' initial head-to-head comparison of two systematically selected and markedly different multi-attribute utility instruments, namely the AQoL-8D and EQ-5D-5L, for a cross-sectional study of patients who received bariatric surgery in the private healthcare system many years previously. Appendix 3A contains the published article [28].

Chapters 4 and 5 are longitudinal studies that were based on a unique cohort of long-term waitlisted patients who were then provided with bariatric surgery. The choice of multi-attribute utility instruments for these studies were guided by the systematic review (Chapter 2) and the findings of Chapter 3. Chapter 5's head-to-head comparison study extended the method of Chapter 3's comparison of the two instruments. Appendices 4A and 5A contain the published articles [26, 27].

Chapters 6 and 7 present health economics studies that adopt qualitative research methods. The inspiration for the method of these studies was partly directed by the systematic review

(Chapter 2) that identified the limited scope of costs and consequences for most health economics reporting of bariatric surgery. Appendix 6A contains the published article from Chapter 6 [128].

Chapter 8 presents a quantitative cost-outcome study that was supported by a strategic research alliance with our Tasmanian State Government partners. A request for revisions has been received from *PharmacoEconomics Open* for the paper presented in Chapter 8.

Chapter 9 presents a summary of this thesis, the conclusions of the research and the most promising directions for future research.

Finally, Appendix 1 presents scholarly output that has been generated from this PhD research and thesis.

1.10 Summary of scholarly output as a direct result of this thesis

This PhD project has resulted in five publications in health economic, quality of life and disease-specific international journals (Chapters 2, 3, 4, 5 and 6 [26-28, 61, 128]), and two manuscripts have been submitted to international journals (Chapters 7 and 8). The relevant findings of each of the seven papers of this PhD project and thesis have been presented at national and international conferences. One of the published papers (Chapter 2) was also identified by a leading national private and public hospital group for an invited presentation at their National Conference and a letter of thanks was received for my presentation. Poster presentations regarding Chapters 4, 5 and 8 were awarded a prize at a highly-regardedinternational conference.

During my PhD research I have also been identified as an expert in my field. I have been invited to peer-review 5 publications (4 subsequently approved for publication) for 3 leading international journals, namely, *Value in Health* (2 publications), *Diabetes Medicine* (2 publications) and *PharmacoEconomics Open* (1 publication).

My PhD research has also generated other scholarly projects with our critical health partner at the conclusion of this PhD project including a broader analysis of all long-term waitlisted patients who subsequently received elective surgery in the Tasmanian public health system due to a public policy decision to reduce waiting lists. Additionally, due to this thesis' publications and advice, the AQoL-8D is being used for important research in other complex and chronic disease areas such as Multiple Sclerosis with translatable research findings.

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Chapter 2: Diverse approaches to the health economic evaluation of bariatric surgery: a comprehensive systematic review

Preface

This chapter provides a comprehensive systematic review of the health economic evaluation of bariatric surgery from 1995 to 2015 (77 included studies). The findings of this published study informed many aspects of the remainder of this thesis, the work program for the NHMRC partnership project, and future directions for research beyond this thesis.

Our study aimed to provide a systematic and critical analysis of the key themes and evidence gaps in the existing scholarly literature. Unlike previous systematic reviews we did not seek to capture homogenous studies for meta-analysis to inform a further cost-effectiveness study. As an important advance on existing systematic reviews, we aimed to adopt a broader approach to our systematic review with a view to identifying common themes and key evidence gaps across the depth and breadth of the health economics literature pertaining to bariatric surgery.

We adopted a suite of gold-standard validated guidelines to assist with the systematic review's data capture, extraction and interpretation.

Some of the findings of the systematic review that guided this thesis were that only 13% of included studies adopted a broader societal perspective, the cost of complications and reoperations for bariatric surgery were not included in one-third of studies and when they were included, conservative estimates were generally adopted, out-of-pocket costs were largely ignored, the EQ-5D suite of multi-attribute utility instruments was prevalent in the health economic evaluation (cost-utility analyses) of bariatric surgery, and that only one study investigated publicly waitlisted patients.

The systematic review's quality appraisal against the Consolidated Health Economic Evaluation Reporting Standards checklist found heterogeneous approaches, inconsistent quality and key evidence gaps in the health economic reporting of bariatric surgery. A key evidence gap from the quality appraisal included that the estimation of resources and costs was deficient.

One of the key findings for NHMRC partnership project was that psychosocial health is a key driver for the success of bariatric surgery. The studies contained in Chapters 3, 4 and 5 use a multi-attribute utility instrument that particularly assesses and captures psychosocial health-related quality of life for people with complex physical and psychosocial needs The choice of the two multi-attribute utility instruments for these studies was a direct result of the systematic review's finding that most cost-utility analyses regarding bariatric surgery used the EQ-5D-5L multi-attribute utility instrument.

This systematic review called for a more comprehensive investigation and reporting of health economic outcomes of bariatric surgery to identify aspects of the bariatric surgery patient's journey that reached well beyond the primary surgery's direct medical costs. Chapters 6 and 7 harnessed the unique advantages of qualitative research methods to identify and contextualise crucial costs and consequences of bariatric surgery that have typically be omitted, or not provided with sufficient priority in the health economic investigation and reporting of bariatric surgery.

The findings of the systematic review also informed the study in Chapter 8, including the investigation of the cost of complications and reoperations for bariatric surgery and robust unit costing methodologies (based on Australia's Activity Based Funding model).

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The published article found at the end of this chapter has been removed for copyright reasons.

Summary

Background: Health economic evaluations inform healthcare resource allocation decisions for treatment options for obesity including bariatric/metabolic surgery. As an important advance on existing systematic reviews, we aimed to capture, summarise and synthesise a diverse range of economic evaluations on bariatric surgery.

Methods: Studies were identified by electronic screening of all major biomedical/economic databases. Studies included if they reported any quantified health economic cost and/or consequence with a measure of effect for any type of bariatric surgery from 1995 to September 2015. Study screening, data extraction and synthesis followed international guidelines for systematic reviews.

Results: Six thousand one hundred eighty-seven studies were initially identified. After two levels of screening, 77 studies representing 17 countries (56% USA) were included. Despite study heterogeneity, common themes emerged, and important gaps were identified. Most studies adopted the healthcare system/third-party payer perspective; reported costs were generally healthcare resource use (inpatient/shorter-term outpatient). Out-of-pocket costs to individuals, family members (travel time, caregiving) and indirect costs due to lost productivity were largely ignored. Costs due to reoperations/complications were not included in one-third of studies. Body-contouring surgery included in only 14%. One study evaluated long-term waitlisted patients. Surgery was cost-effective/cost-saving for severely obese with type 2 diabetes mellitus. Study quality was inconsistent.

Discussion: There is a need for studies that assume a broader societal perspective (including out-of-pocket costs, costs to family and productivity losses) and longer-term costs (capture reoperations/complications, waiting, body contouring), and consequences (health-related quality of life). Full economic evaluation underpinned by reporting standards should inform prioritization of patients (e.g. type 2 diabetes mellitus with body mass index 30 to 34.9 kg/m^2 or long-term waitlisted) for surgery.

2.1 Introduction

2.1.1 The health and economic burden of obesity

Obesity is not only a major health concern, it is also an economic problem [1]. Excess weight gain is forecast to lead to an increased health burden from several diseases, most notably cardiovascular diseases, diabetes and cancers [1]. The economic burden of the obesity epidemic is substantial and far-reaching and includes the increase in medical and other obesity-related expenditures [1], decreased workplace productivity [2], negative impacts on family and relationships [3] and stigmatization and discrimination of the overweight and obese both individually and collectively [4].

Overweight and obesity in adults is commonly classified with body mass index (BMI) calculated as BMI = weight (kg)/height (m^2). For adults, BMI ≥ 25 kg/m^2 is classified as overweight and BMI ≥ 30 kg/m^2 is obesity [5]. Worldwide prevalence of obesity has doubled since 1980 [5], and based on the latest available surveys, more than half (53%) of the adult population in the Organisation for Economic Co-operation and Development is estimated to be overweight or obese [6]. Among those countries where height and weight were measured, the proportion was even greater at 57% [6]. Furthermore, severe obesity (BMI ≥ 35 kg/m^2) is increasing faster than obesity in adults and children [7].

A recent ground-breaking econometric study suggests that self-reported weight consistently underestimates the effects on government costs [8]. The study adopted the econometric instrumental variables approach to investigate the possibly causal effect of obesity on medical care costs by adjusting for endogeneity of weight (the correlation of obesity with medical care costs where the model may be informed by an under or over estimate of costs) and measurement error in weight (replace self-reported height and weight) [8]. Importantly, this study implied that previous widely cited estimates have underestimated the causal impact of obesity on medical care costs. In turn, this implies underestimates of the economic rationale for government intervention to reduce obesity-related costs [8]. Treatments for overweight and obesity include dietary therapy, exercise/behavioral interventions, weight loss medications and bariatric (weight loss/metabolic [9]) surgery [10]. Bariatric surgery is a well-documented treatment for obesity worldwide with increasing prevalence in developed and developing countries, and the types of metabolic/bariatric operations are in continuous flux with different surgical options continuously evolving influenced by literature results, specific local conditions and the experience of surgical staff [11-13]. Many clinical and epidemiological studies have found that all types of bariatric surgery are clinically effective particularly for patient subgroups such as the severely obese and severely obese with type 2 diabetes mellitus (T2DM) [14]. As a rapidly evolving subspecialty of gastrointestinal surgery, bariatric surgical procedures involve gastric restriction (to augment early satiety and limit meal portions) or intestinal diversion (designed to reduce caloric absorption). Some bariatric procedures contain elements of restriction and diversion [15]. Bariatric medicine has developed as a clinical subspecialty in some countries, and others are calling for this level of specialization as a treatment option for obesity [16].

2.1.2 Economic evaluation of bariatric surgery

Economics is a discipline concerned with the existence of limited resources and unlimited human wants and desires. Without enough resources to satisfy all the desires of all people, the challenge arises how to allocate those available resources among competing objectives [17]. Economic evaluation is defined as *the comparative analysis of alternative courses of action in terms of both their costs and consequences*. Economic evaluation is a vital resource allocation methodology because it provides decision makers with robust analyses to underpin decisions about committing scarce healthcare resources to one use instead of another [18]. An economic evaluation needs to identify, measure, value and compare the costs and consequences of the alternatives being considered [18].

A recent study that investigated the incorporation of economic evidence and perspectives in Cochrane reviews argued that questions such as 'at what cost is the outcome achieved?', and 'what will be the economic impact of this intervention?' are crucial if health systems are to use the resources they have available to their best advantage [19]. Many full economic evaluations conclude that bariatric procedures are a cost-effective treatment option for obesity [20-26]. In contrast, a recent critique opined that accumulating evidence suggested no economic benefit for bariatric surgery [27]. The critique also called for the consideration of patients who have a complication of obesity that was known to dramatically improve with weight loss surgery (e.g. diabetes and osteoarthritis) [27]. Further, for an intervention to be cost-effective, ability as well as willingness to pay must be met. The aim of this systematic review is to explore these conflicting observations.

Specifically, our systematic review aims to: map what research has been conducted; identify common themes among heterogeneous studies; identify the major 'knowledge gaps' [28] by classifying and critically analysing variables that underpin both partial and full economic evaluation and by detailed investigation of the health economic metrics of full economic evaluation; and describe the overall quality of the research. It will also identify patient subgroups where bariatric surgery is found to be largely cost-effective and patient subgroups that warrant further health economic investigation. To date, systematic reviews of health economic outcomes for bariatric surgery have generally adopted narrow eligibility criteria and reported on limited primary studies, or have selected homogenous studies to retrieve data to model cost-effectiveness [15, 29-32]. Other systematic reviews have restricted eligibility by assuming criteria such as long-term modelling of cost-effectiveness [33]. As an important advance on existing systematic reviews, our review adopts broad eligibility criteria to capture a disparate and comprehensive range of health economics studies that have investigated bariatric surgery as a treatment option for obesity.

2.2 Methods

2.2.1 Validated guidelines

This systematic review has been performed and reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines [34]. The Campbell and Cochrane Economics Methods Group guidelines to incorporating economic evidence in reviews informed the bibliographic database search criteria, data extraction and synthesis [35].

No previous systematic review has critically appraised health economics evaluations for bariatric surgery for methodological quality against the Consolidated Health Economic Reporting Standards (CHEERS) statement [36]. The CHEERS statement consolidates previous health economics evaluation guidelines into one current useful reporting guidance and recognizes that economic evaluations require additional reporting space [36]. Included studies were graded as high, medium and low quality. All of the 24 items were given equal weight. For full economic evaluations, 20–24 points of the 24 point checklist were categorized as high quality, 15–19 points were deemed to be of medium quality and ≤14 points ranked as low quality (<60%). Methodological quality of partial economic evaluations was also considered, and percentages were calculated on a pro-rata basis where <60% of the relevant CHEERS statement for the particular study was rated low quality, 60–80% medium quality and >80% high quality.

2.2.2 Bibliographic databases and search terms

A predefined search strategy was used to identify relevant articles published in both health economics and biomedical databases from 1995 to September 2015. Seven economic databases – American Economic Association (EconLit), Ideas, the Centre for Reviews and Dissemination (CRD), which includes the Database of Abstracts of Reviews of Effects (DARE), Health Technology Assessment Database (HTA), National Health Service Economic Evaluation Database (NHS EED) and the Cost-Effectiveness Analysis Registry (CEA Registry) and four biomedical databases – PubMed, MEDLINE, Embase and Scopus were initially searched between June–September 2014. A further search was conducted in September 2015 to capture studies from September 2014 to September 2015. Search terms were adopted from the databases' vocabulary tools where available such as Medical Subject Headings (MeSH terms) for PubMed/MEDLINE including ‘health care economics and organisations’ and ‘bariatric surgery’ and ‘quality of life’ and Emtree terms for EMBASE including ‘bariatric surgery’, ‘economic aspect’ and ‘quality of life’. Scopus and the economic databases do not contain vocabulary tools, and the appropriate search terms were grouped together adopting the PICO convention, which references participants, interventions, comparisons and outcomes [37]. An example of the search strategy is provided in Table 1. To identify other relevant studies, a key word search of Google Scholar, citation lists and the bibliographies of review articles and the obtained studies were also scrutinized.

Table 1: Search strategy based on Preferred Reporting Items for Systematic Reviews and Meta-Analyses methodology

Long Search	#1 AND #2 AND #3 NOT #4
#1 Economic filters (outcome)	"economic evaluation" OR cost OR effectiveness OR "cost effectiveness" OR "cost benefit" OR "cost analysis" OR "cost utility" OR CUA OR CBA OR CEA OR "health economic*" OR economic* OR "direct cost" OR "indirect cost" OR "intangible cost" OR "health care cost" OR " OR "quality adjusted life year" OR QALY OR utility OR "economic benefit" OR "economic evaluation" in Title, Abstract or Keywords (outcome);
#2 Participant/ #3 Intervention	"bariatric surgery" OR "obesity surgery" OR "metabolic surgery" OR "weight loss surgery" OR "laparoscopic adjustable gastric band" OR "swedish adjustable gastric band" OR "gastric bypass" OR LAGB OR SAGB OR RYGB OR VGB OR "roux-en-Y" OR "gastric sleeve" in Title, Abstract or Keywords (participant and intervention);
#4 Excluding	NOT "animal" in Title, Abstract or Keywords
MeSH and Emtree Search	("Health Care Economics and Organizations" explode all trees [MeSH] AND "Bariatric Surgery" explode all trees [MeSH]; "Bariatric Surgery" explode all trees [MeSH] AND "Quality of Life" explode all trees [MeSH])
	("Bariatric Surgery" explode all trees [Emtree] AND "Economic Aspect" explode all trees [MeSH]; "Bariatric Surgery" explode all trees [MeSH] AND "Quality of Life" explode all trees [Emtree])

2.2.3 Study eligibility, selection of studies and data extraction

Studies were included if they satisfied the criteria, (1) reported a quantified cost and/or consequence with a measure of effect for no surgery, 'before and after', conventional treatment or standard care (studies that only compared costs of one type of surgery against another type were excluded), for any type of bariatric surgery such as laparoscopic adjustable gastric banding (LAGB), Swedish adjustable gastric banding, vertical gastric banding, gastric banding, vertical banded gastroplasty, sleeve gastrectomy, gastric bypass and Roux-en-Y gastric bypass; (2) reported in English in the scholarly literature, and (3) participants include adults, adolescents or children. Other systematic reviews, studies that report health-related quality of life or health state utility only and studies that do not report an effect, were excluded.

From the initial yield, search results were put through two levels of screening prior to data extraction. Initial screening was open ended to retain as many relevant studies as possible. Titles and abstracts were screened for evidence of health economic analyses including cost and cost analysis, cost-effectiveness analysis, cost-utility analysis and cost-benefit analysis, or health economics metrics such as changes in costs before and after surgery, costs per quality adjusted life year, costs per life year saved, costs per disability adjusted life year, time to breakeven or quantified changes in work productivity. A random sample of included and excluded studies after the initial screening was independently reviewed by two co-authors. After removing studies that fit the exclusion criteria during the first level of screening, the full text of the remaining studies was assessed against the inclusion criteria and any disagreements were resolved by consensus.

2.2.4 Data extraction

Data were extracted on authorship, year of origin, country of origin, type of bariatric surgery, study design, sample size, study population, discount rate, classification of studies as partial or full economic evaluations, health economics perspective (healthcare system/third-party payer, societal, not stated), time horizon, comparator (including before and after surgery), currency, clinical effectiveness measures, costs including costs of the initial procedure, healthcare resource use (hospital and community care), patient and family (out-of-pocket expenses [excluding direct medical], travel time, direct care giving) resource use in other sectors (including work productivity and pension status), cost-effectiveness and cost-utility metrics (e.g. incremental cost/quality-adjusted life year (QALY) gained, cost/life-year saved, cost/case T2DM remitted), reoperations, complications or body contouring surgery were also reported separately, and key summary measure(s) and key conclusion(s).

The definitions of partial and full economic evaluations, willingness to pay thresholds, health economics perspective and costs were derived from standard health economics sources [18, 35]. Reoperations and complications were classified as any re-operative/revisional procedure or complication following the primary procedure (including peri-operative complications).

2.3 Results

2.3.1 Screening for study eligibility

The electronic search yielded 6,187 studies. Biomedical databases generated 5940 studies, and economic databases generated 241 studies. A further six studies were identified through other sources. After removal of duplicates, 4,474 studies' titles and abstracts were reviewed against the eligibility criteria, and 4,216 studies were excluded. Two hundred fifty-eight full text articles were then assessed for eligibility and 181 were excluded, leaving 77 included studies. Figure 1 provides results of the search strategy based on Preferred Reporting Items for Systematic Reviews and Meta-Analyses methodology.

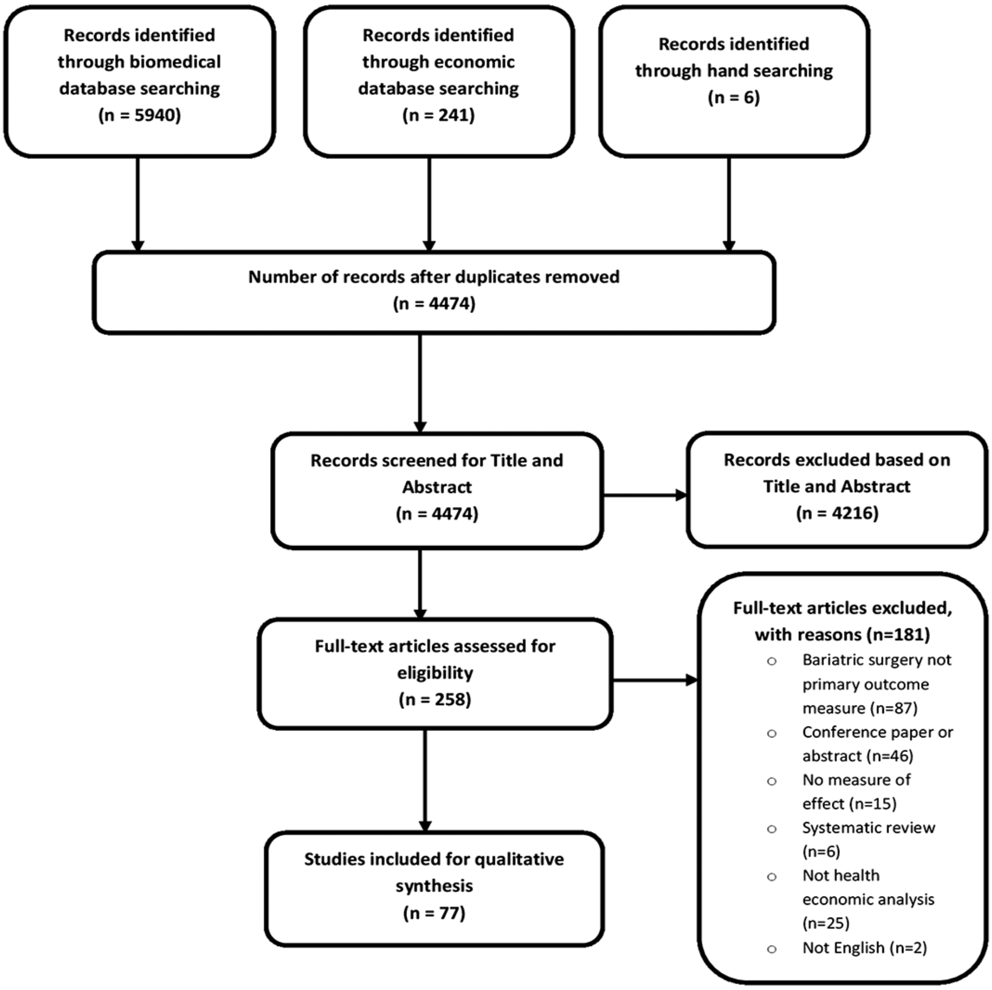

Figure 1 Results of search strategy based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses methodology.

2.3.2 Overlap with previous systematic reviews

The six previously performed health economic systematic reviews noted in our study contained 29 studies. Our review contained 21 of these studies: the other eight did not satisfy our broad eligibility criteria. Twenty-one of these studies were published before 2009, and 16 of these studies were cost-effectiveness or cost-utility studies. Our review included 46 studies from 2010 to 2014; 18 of these studies were full economic evaluations, and 28 were partial economic evaluations (eight of the full economic evaluations were included in the previously performed studies).

2.3.3 Overview and synthesis of included studies

A comprehensive description of the characteristics of all the included studies is shown in Table 2. Subgroup analyses of included cost-effectiveness and cost-utility studies from 2009 stratified into diabetes cohort-specific studies and severe obesity cohort/s studies are provided in Tables 3 and 4, respectively. Willingness to pay thresholds for different jurisdictions are reported in Table 4. The tables are provided at the end of the Results section.

2.3.4 Distribution of region and type of surgery

Studies also originated from Sweden [43, 84, 87, 90, 106, 114] 10% ($n = 8$), Australia [65-67, 75, 97, 99] 8% ($n = 6$), UK [54, 58, 95, 96, 100, 101] 8% ($n = 6$), Canada [45, 49], and the remainder of the included studies each for France [54, 105] ($n = 2$),Germany [54], (Austria, Italy, Spain) [63], Spain [21], Norway [74], Portugal [93], the Netherlands [40, 57], Finland [25], South Korea [102], Brazil [80, 91] ($n = 2$) and Mexico [92]. Two studies reported data from three countries [54, 63] (Table 2).

Reporting of bariatric procedures has evolved according to the relative distribution of procedures for the timeframe [11, 13]. In line with technical change [11, 115], included studies from 1995 to early 2000 largely reported on open procedures such as Roux-en-Y gastric bypass, vertical banded gastroplasty and gastric bypass. Laparoscopic procedures such as LAGB and laparoscopic Roux-en-Y gastric bypass (LRYGBP) are reported from the early 2000s (Table 2).

2.3.5 Time horizon

Seventy six studies reported a time horizon. Of those that reported a time horizon, 42% ($n = 32$) adopted a timeframe of ≤5 years [39, 44-51, 54-59, 61, 63, 65, 70, 73-75, 79, 80, 85, 86, 91, 95-98, 100, 105] and 53% of these studies reported results for ≤2 years ($n = 17$) [44, 46-48, 50, 51, 55-58, 61, 65, 74, 80, 86, 95, 96, 98] (mostly cost and cost analyses). Some cost and cost analyses reported a longer time horizon of 6–10 years ($n = 12$, 16%) [38, 43, 53, 69, 72, 81, 83, 88, 89, 103, 107, 114] or 11–20 years ($n = 3$, 4%) [87, 90, 94]. In these studies, there was a significant loss of participants to follow-up in the later years for large samples [38, 83, 103] or analyses were informed by a small sample from a single study centre [56]. Modelling studies that generated cost-effectiveness or cost-utility metrics ($n = 25$, 33%) [10, 20-22, 24, 26, 40, 42, 52, 54, 57, 60, 62-68, 71, 93, 99, 100, 102, 104] generally extrapolated data from 2 to 5 years to longer term or lifetime [21, 24, 26, 40, 42, 66, 71, 93, 101], 10 years [82, 92] or <10 years [54] (Table 2).

2.3.6 Study design and study population

Just under half of the included studies adopted a retrospective, observational study design ($n = 35$, 45%) [38, 44, 45, 47-51, 53, 56, 60, 61, 69, 70, 72, 75, 76, 78-81, 83, 85, 86, 88, 89, 91, 94-97, 103, 105, 107], and 34% of these studies originated from the USA. Cohort matching techniques included studies that matched the surgical cohort with a control by adopting rigorous propensity score matching methodologies [78, 88, 103, 116] or other methodologies by matching particular variables such as comorbidity (most commonly T2DM and cardiovascular) and/or age and gender [89]. Two health economics studies were particularly embedded within a randomized control trial (RCT) [65, 66]. Nested cohorts from the Swedish Obese Subjects study investigated costs of in-patient care [41], sick leave and disability pension [39, 87], medication costs [117] and healthcare costs for patients with differing baseline glucose status [106]. Just over one-third of studies utilized modelling techniques to facilitate a full economic evaluation of the intervention ($n = 29$, 38%) [2, 10, 20-22, 24, 26, 40, 42, 52, 54, 62-64, 66-68, 71, 73, 77, 82, 84, 92, 93, 99-102, 104]. Some collected economic data prospectively [46] (Table 2).

The target population was generally the severe and/or morbidly obese [26, 60] middle-aged females [52, 71, 72, 91]. Studies that specifically targeted an obese male cohort included Veterans Administration studies [44, 69, 86, 88], and this study population was generally clinically more unwell with an additional or more severe comorbidity load than a corresponding female cohort [44, 88]. In contrast, other studies focused on a healthier cohort with no or limited comorbidities [42, 91]. Health economic metrics for people with T2DM [24, 47, 54, 63-66, 68, 70, 76, 81-83, 91, 93, 100, 101, 106] were investigated, and recent studies stratified this subgroup further into established versus newly diagnosed people with diabetes [65, 68] (Table 2, Table 3). Another recent study stratified patient groups according to baseline glucose status (euglycaemia, prediabetes and diabetes) [106]. A subgroup that also emerged as an important target population were severely obese adolescents, however, only two studies met the eligibility criteria albeit with limited data [67, 104]. Particular ethnic groups were also reported including Native Hawaiians [98] and South Koreans (or a predominantly Asian population) [102].

2.3.7 Data sources

The Data sources included single site administrative data (hospital administrative data and medical records) [89, 95], large private insurance claims data or health plan data [70, 71, 103], data linkage of government (tax-funded) insurance schemes [97], national surveys [68, 85], cost diaries [57], direct contact with physicians or primary care providers to augment administrative data [96], questionnaires [58], peer-reviewed journal articles [100], technical reports [54] and RCT data [65]. Many included studies sourced retrospective, longitudinal data from large administrative databases [22, 49, 60, 61, 69, 70, 78, 88, 103] and/or from a single hospital site [64, 86, 91, 95]. Studies from the USA analysed retrospective administrative data from either a single tertiary site or a large private insurance plan [70, 78, 83]. Two recent studies from the USA explicitly used a comparison sample that was not restricted to the morbid obesity diagnosis code [88, 94] (Table 2).

2.3.8 Economic evaluation

Included studies reported the results of 87 partial or full economic evaluations including cost and cost analysis ($n = 41$, 53%) [38-40, 43-51, 53, 55, 56, 58, 59, 61, 69, 70, 72, 74, 75, 80, 83, 86-91, 95-98, 100, 103, 105-107, 114] cost-effectiveness analysis ($n = 12$, 16%) [10, 20, 26, 42, 54, 57, 63-67], cost-utility analysis ($n = 23$, 29%) [10, 21, 22, 24, 26, 40, 42, 52, 54, 57, 62-64, 66-68, 71, 82, 93, 99, 101, 102, 104], cost-benefit analysis ($n = 3$, 4%) [2, 73, 77] and return on investment ($n = 8$, 10%) [60, 73, 76, 78, 79, 81, 85, 94]. We found a cost analysis that claimed that bariatric surgery could be cost-effective when effectiveness measures were not included in the analysis [95].

Studies classified as partial economic evaluations reported health economics metrics such as cost per pound of weight loss [38], changes in preoperative and postoperative mean and/or median healthcare costs (including inpatient, laboratory tests, specialist visits, operating theatre, outpatient follow-up, medications) [70, 89] at particular time horizons (such as preoperative, post-operative monthly, six monthly and 12 monthly), changes in comorbidity-related medical expenses including medications [46, 50, 56, 61, 86, 90, 97] (prescribed and over-the-counter) and equipment (CPAP machinery [47]). Studies classified as full economic evaluations reported metrics such as cost per quality-adjusted life year [52, 93], cost per life year saved [66], cost per disability adjusted life year [67], cost per T2DM free year [63], cost per case of T2DM remitted [65], time to breakeven [2] or net benefit [2] (Tables 2, 3 and 4).

The first included study to conduct a full economic evaluation of bariatric surgery was published in 1999, and this study was underpinned by clinical and cost data from 21 participants [40]. The first widely cited robust study to conduct a full economic evaluation of treatment versus no treatment for bariatric surgery was published in 2002 [42]. This study adopted a deterministic decision model to compare the lifetime expected costs and outcomes between gastric bypass and no treatment of severe obesity from the payer perspective. Modelling studies were more prevalent since 2008, and modelling methodologies ranged from simple and complex decision tree/s [40, 52, 63], Markov models with memory or no memory [24, 64, 66-68], simulation models [2, 71, 92] and a combination of these approaches [82, 102]. These studies investigated the cost-effectiveness of different types of bariatric surgery compared with no surgery (do nothing [99]), standard care (e.g. T2DM) [66]) and medical management (e.g. intensive supervised very low-calorie diet regime [38]) (Tables 2, 3 and 4).

2.3.9 Reporting of study perspective

The perspective adopted was reported in 62% ($n = 48$) [2, 10, 20, 21, 24, 26, 40, 42, 44, 52-55, 57, 60, 62-67, 69, 71-73, 76-78, 80-84, 86, 88, 89, 91-93, 97-102, 104, 105] of studies. Of these studies, only 13% ($n = 10$) [2, 20, 40, 52, 57, 67, 73, 77, 93, 99] reported employing a societal perspective. A healthcare system/third-party payer perspective was reported for 53% ($n = 41$) [2, 10, 21, 22, 24, 26, 42, 44, 53-55, 60, 62-66, 69, 71-73, 76, 78, 80-84, 86, 88, 89, 91, 97-102, 104, 105] with three studies reporting more than one perspective [2, 73, 99]. Studies that did not explicitly report a perspective ($n = 29$, 39%) [38, 39, 43, 45-51, 56, 58, 59, 61, 68, 70, 74, 75, 79, 85, 87, 90, 94-96, 103, 106, 107, 114] generally adopted a healthcare system or third-party payer perspective (Table 2).

2.3.10 Reporting of clinical effectiveness

Effectiveness measures included health state utility values [22], percentage change in excess weight loss [57], change in BMI [72], percentage change in weight, medication consumption for comorbidities such as hypertension and diabetes mellitus [75], use of specialized equipment for sleep apnoea, systolic and diastolic blood pressure, and biochemical measures such as HbA1c and lipids [100]. Cost-effectiveness and cost-utility studies all reported effectiveness measures. Some partial economic evaluations also reported effectiveness measures separately [61, 86] (Table 2).

2.3.11 Reporting of costs

Reporting of costs for bariatric surgery was considerably heterogeneous. Levels of precision in the identification, measurement and valuation of costs ranged from micro or unit costing [100], average per diem costs [2, 95], seeking an expert opinion from surgeons/physicians/primary care providers [82, 102] or a combination of these approaches [54, 102]. Sample sizes ranged from 21 participants to over 29,000 participants at baseline, and at least one study concluded that a ‘small sample size’ precluded definitive findings [55] (Table 2).

Healthcare resource/sector costs only (including hospital and primary care) were reported in just over three-quarters (77% [*n* = 58]) [10, 21, 22, 24, 26, 38, 42-46, 48-51, 53-56, 60-66, 68-70, 72, 75, 76, 78, 80-84, 86, 88-92, 94-98, 100-106, 114] of the included studies and were generally limited to inpatient (including readmissions) and shorter-term outpatient costs [38, 49, 52, 81, 95, 114]. Many studies reported changes in mean hospital costs (e.g. hospital care, hospital bed days, intensive care unit, nursing, medications and operating theatre) [41, 44, 69, 114]. Two studies investigated changes in median costs [70, 83].

Studies that investigated changes in medication costs only ($n = 10$, 13%) [43, 46-48, 50, 56, 75, 86, 97, 98] were commonly sub-stratified into obesity-related comorbidities such as diabetes mellitus, cardiovascular disease, sleep apnoea and gastroesophageal reflux [46, 47, 97]. One study investigated changes in prescription medication costs for LGBP patients and considered a total of 81 unique medications used to treat 21 different medical conditions [46]. Another study investigated changes in medication use for an older cohort (>60 years) [75]. One study considered Native Hawaiians' prescription medication costs after LRYGBP [98].

More specifically, two studies that reported average monthly medication costs for a 2-year time horizon found a decrease in costs of 69% for diabetes medications (both studies) and a decrease in costs for cardio-vascular medications by 31% and 43% [43, 118] A recent study found that over a 1-year time horizon the annual costs of medications to treat diabetes were reduced by 88% and hypertension medication costs were reduced by 65% [86]. Interestingly, the same study investigated a subset of patients with persistent hypertension and/or diabetes and subsequently found a decrease in costs of 69% in diabetes medications and 58% for anti-hypertensives. Another study that investigated medication costs over a 4-year time horizon (2006–2009) for the entire Australian population that underwent LAGB surgery ($n = 6040$) found that the greatest absolute cost reductions in year two after LAGB were observed in medications to treat diabetes (47% reduction) and cardiovascular disease (17% reduction) [97]. In contrast, a recent Australian study that reported on the medication usage for an older cohort (>60 years) found that there was not a significant average medication reduction for obesity-related comorbidities over the time of the study (2 years) [75]. Another study concluded that surgical obesity treatment lowers diabetes mellitus and cardiovascular medication costs but increases other medication costs (such as gastrointestinal tract disorder, anaemias and vitamin deficiency medications), resulting in similar total costs for surgically and conventionally treated obese individuals for 6 years [43].

Patient and family costs and other sector costs were reported in a minority of studies (*n* = 19, 25%) [2, 20, 39, 40, 52, 57-59, 67, 71, 73, 74, 77, 79, 85, 87, 93, 99, 107]. These costs comprised out-of-pocket costs to the individual (ranging from self-pay for the primary procedure, travel time [99] to incidental out-of-pocket costs) and costs to family members (such as direct care giving [58] or travel time) and were largely ignored. Similarly, there was a dearth of information on other sectors. However, a few studies investigated work productivity/participation [57, 74, 77], absenteeism, presenteeism [85] and pension status as a proxy for work productivity [39, 58, 59, 87]. To illustrate, a recent US-based study estimated the time to breakeven and 5-year net costs of LAGB taking both medical costs and costs arising because of absenteeism and presenteeism (productivity impacts) into account. The study found that by including productivity impacts, the time to breakeven was reduced by 6 months. After 5 years, the inclusion of absenteeism and presenteeism increased savings by $4,780. Another study examined the cost-effectiveness of providing LAGB surgery to all morbidly obese adults in 2003 for the Australian population. The study incorporated conservative estimates of time for travel and travel costs where patients' time only was valued at 25% of the hourly wage rate and calculated based on the proportion of the Australian population employed, unemployed or not in the workforce. The study found that when LAGB surgery was extended to all Australians with BMI > 35 kg/m2, the mean incremental cost-effectiveness ratio (ICER) becomes $2,154/disability-adjusted life year averted. However, when time and travel costs for procedures and consultations were included for people BMI > 35 kg m^{-2}, the change was $4,102/disability-adjusted life year averted ($417–$8,720).

The cost(s) of waiting for surgery (wait-listed patients in the public sector) was not considered in 76 studies [24]. A recent study claimed to be the first to attempt to quantify the potential impact of extensive waiting lists on both health costs and clinical outcomes [24]. The study analysed the consequences of a 3-year delay in providing bariatric surgery and revealed that the overall lifetime cost in the surgical arm may be slightly reduced in non-diabetic patients with moderate and severe obesity (BMI < 40 kg m^{-2}), but the cost was increased in non-diabetic patients with morbid or super-obesity and people with diabetes (increase from €23 to €2,803).

Comprehensive assessment of costs encompassing all sectors as incurred by the health system and patient and family and other sectors were reported in only 18% ($n = 14$) [2, 20, 40, 52, 57, 67, 71, 73, 77, 79, 85, 93, 99, 107] of included studies. One of these studies found that the total social value for bariatric surgery was large for treated patients with incremental total social cost-effectiveness ratios typically under $10,000 (USD) per life year saved. The study found that the net social effect was large once improvements in life expectancy are taken into account [20].

2.3.12 Reporting of costs of complications and reoperations, and body contouring surgery

The consideration of reoperations and complications following the primary procedure were not included in one-third of studies ($n = 25$, 33%) [2, 21, 38, 43, 47, 48, 56, 58, 59, 61, 70, 76, 77, 81, 83, 86, 87, 91, 92, 97, 98, 104, 107]. Moreover, many studies that included complications and/or reoperations adopted a relatively short timeframe or assumed a probability of the event occurring as low. One study particularly investigated the requirement for intensive care support (and associated costs) either electively or emergently for primary (210 patients) or revisional (31 patients) procedures [51, 120]. The development of complications significantly affected the hospital cost, for example, the development of deep vein thrombosis or pulmonary embolism increased the cost from mean (SD) USD 29,290 ± 55,000 to 93,000 ± 77,700. This study also found that approximately 40% of patients that required intensive care unit admission/s were men.

The available evidence regarding the cost of complications (including early and late, minor and major) was inconsistent. Nevertheless, some of the included studies in our review provided estimates of these costs. Two studies that robustly quantified the costs of complications and reoperations over the short, medium and longer terms established that these ongoing costs could be higher than the cost of the initial procedure [26, 103]. The cost of the primary procedure ranged from $7,042 (2011 USD) for LAGB in South Korea, to $11,290 (2003 AUD) in Australia and to $26,315 (2011 USD) as an average cost for all procedures (Table 4). A full economic evaluation that estimated costs for early, late, minor and major reoperations and complications estimated a range of $426 to $41,708, with a cost of a late moderate reoperation for LAGB $11,115 (probability 4.9%) and LRYGBP $14,328 (probability 8.6%) (2006 USD) [26]. Similarly, a recent partial economic evaluation explored 6-year follow-up costs in surgery patients with a control group based on inpatient admissions (by DRG) recorded in a large US insurance administrative database. The study showed that the surgical group had significantly more admissions for digestive-related diagnoses in all six post-operative periods (annually for 6 years) relative to the comparison group. The study assumed that a significant proportion of these admissions were likely follow-up procedures for bariatric surgery-related complications. The mean (SD) quantified costs for the surgical group's inpatient costs years 1 to 6 (USD 2005) were year 1: $4,193 (15,512), year 2: $5,186 (15,935), year 3: $4,666 (16,045), year 4: $4171 (15,766), year 5: $4,302 (16,979) and year 6: $4,407 (23,166) (103). Clearly, these costs are substantial and approach the cost of the initial procedure. In contrast, a recent cost-effectiveness analysis assumed that the cost of bariatric surgery without complications was €4,915 (range: 3,932–5,898) and the cost of bariatric surgery with complications was €5,766 (4,613–6,919) (2012 EURO) (24).

Body contouring surgery/bariplastic surgery costs [121, 122] were only included in 14% ($n = 11$) [24, 42, 44, 62, 68, 71, 74, 82, 84, 100, 114] of studies, and these costs were substantially underestimated in these studies by limiting costs to abdominoplasty or panniculectomy [24, 42, 44, 62, 68, 74, 82, 84, 100].

2.3.13 Health-related quality of life and health state utility values

Cost-utility studies adopted health state utility values from multi-attribute utility instruments such as the EQ-5D [71], SF 12 or 36 [123] and 15D [25]. The EQ-5D dominated the valuation of health state utility values in these studies [124] (Table 2). Validated bariatric (such as the Bariatric Quality of Life [125]) or gastrointestinal-specific health-related quality of life instruments (such as the Gastrointestinal Quality of Life Index [126]) were generally not adopted; however, a recent cost-effectiveness study adopted the Bariatric Quality of Life [10].

2.3.14 Reporting of cost-effectiveness

Cost-effectiveness and cost-utility studies (from 2009) that investigated people with diabetes (Table 3) found that bariatric surgery was cost-effective and in some cases cost-saving for the severely obese with T2DM [63-66, 68, 101]. All of these studies were undertaken from the health payer perspective, across differing time horizons, and their results were robust to changes in parameter assumptions. One study found that testing of model values and assumptions either maintained the dominant status of surgical therapy or shifted the economic status of surgical therapy from dominant to cost-effective ($13,400/QALY gained 2006 AUD) [66]. Another recent study that stratified a T2DM study population into 16 sub-groups based on sex and BMI classifications across a lifetime time horizon found that bariatric surgery was cost-saving in all four pre-specified diabetic cohorts (moderately, severely, morbidly and super-obese) in both male and female patients. The study's sensitivity analysis also found that the most sensitive parameter of the cost variables was the annual cost of T2DM [24].

Similarly, for the severely, morbidly and super-obese cohorts (generally classified by these studies as 35.0–35.9 kg/m2, 40.0–49.9 kg/m2 and ≥ 50 kg/m2, respectively), bariatric surgery was cost-effective in the base-case analysis [20, 21, 26, 71, 82, 93, 99, 102, 127] (Table 3). Three of these studies adopted a societal perspective [20, 94, 100]. Incremental cost-effectiveness ratios (cost/QALY gained) for cost-utility studies that reported in USD from 2010 to 2014 revealed base-case valuations of ≤$6,500/QALY gained. One study was an exception and reported $17,300/QALY gained for ORYGBP (an open procedure). These valuations still fall well below the accepted willingness to pay threshold of ≤$50,000/QALY (Table 4). Additionally, cost-utility studies that reported in EUROs from 2010 to 2014 found that bariatric surgery was dominant in the base-case analysis. Sensitivity analyses generally showed that these results were robust. One study found that the largest observed changes to base-case analysis occurred after excluding cost offsets and increasing the rates of maintenance and complications; nevertheless, the reported ICER still fell below the jurisdiction's willingness to pay threshold [99]. One of these studies reported the range of complications and reoperations as early, late, minor and major [26].

2.3.15 Methodological quality

Health economics reporting for bariatric surgery was generally deficient when graded against the new CHEERS statement. Table 2 and Figures 2a and b provide the individual scores for included studies and overall quality was ranked as medium. Full economic evaluations generally rated highly against the new criteria ($n = 18$) [10, 21, 22, 24, 26, 42, 54, 57, 62, 64-66, 81, 82, 92, 99, 101, 102] (particularly from 2010). Six partial economic evaluations were rated as low (five studies to 2008 and one study in 2012) [38, 44, 47, 55, 61, 84]. The individual scores revealed that methodological quality has improved over time (Figures 2a and b). Critical appraisal of methodological quality against the CHEERS checklist items revealed that individual items of 'estimating of resources of costs', 'choice of model' and 'assumptions', 'analytical methods' and 'study parameters' were items where studies that rated low to medium generally did not rate adequately against the requirements of the individual criteria.

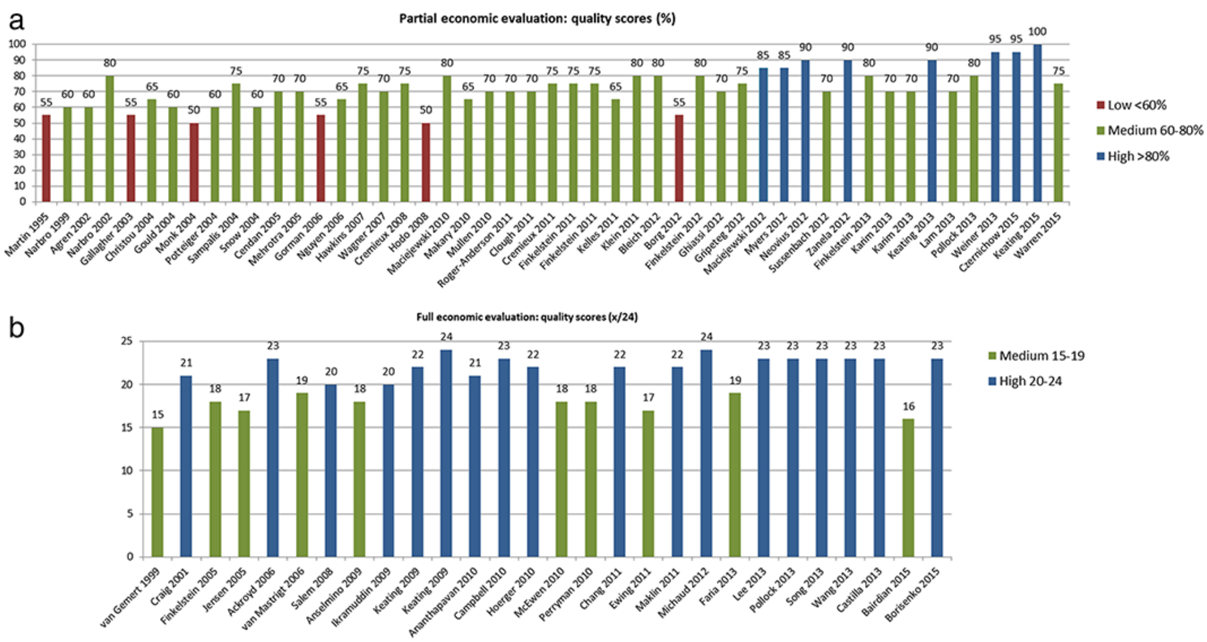

Figure 2: (a) Methodological quality of partial economic evaluations rated against the Consolidated Health Economic Reporting Standards checklist: low (<60%), medium (60% - 80%) and high (>80%). (b) Methodological quality of full economic evaluations rated against the Consolidated Health Economic Reporting Standards checklist: low (≤ 14 points), medium (15 – 19 points) and high (20 - 24 points).

Table 2: Characteristics of included studies (n = 77).

Key: AUD, Australian Dollar; BIA, budget impact analysis; BPD, British Pound; CBA, cost-benefit analysis; CCA, cost and cost analysis; CEA, cost-effectiveness analysis; CM, comorbidity; CT, conventional treatment; CUA, cost-utility analysis; CVD, cardio-vascular disease; DM, diabetes mellitus; DR, discount rate; EURO, Euro; GB, gastric band; GBP, gastric bypass; GERD, gastro-oesophageal reflux disease; GID, gastro-intestinal disease; GP, general practitioner; GST, gastric stapling; HLP, hyperlipidaemia; HT, hypertension; ICER, incremental cost-effectiveness ratio; LAGB, laparoscopic adjustable gastric band; LRYGBP, laparoscopic Roux-en-Y gastric bypass; LSG, laparoscopic sleeve gastrectomy; LY, life years; Meds, medications; MO, morbid obesity code; NHP I and II, Nottingham Health Profile; NSAID, non-steroidal anti-inflammatory drug; ORD, obesity related diseases; PA, physical activity; PD, pulmonary disease; QALY, quality-adjusted life-years; RYGBP, Roux-en-Y gastric bypass; SAH, systemic arterial hypertension; SG, sleeve gastrectomy; SOS, Swedish Obese Subjects study; T2DM', type 2 diabetes mellitus; TC, total costs; USD, United States Dollar; VAMC, Veterans Affairs Medical Centre; VAS, Visual Analogue Scale; VBG, vertical banded gastroplasty.

Author, year, country, currency, time horizon, discount rate.	**Type of surgery.**	**Target group.**	**Main data source(s).**	**Compa-rator.**	**(N=x) at baseline.**	**Health care resource costs (hospital and primary care).**	**Patient and family costs and other sector costs.**	**HRQoL, HSUV.**	**Persp-ective.**	**Reoper-ation, complication, body-contouring (BC)**	**Study design, key effectiveness measure(s), key costs, partial or full economic evaluation.**	**Econ-omic evalu-ation, quality rank and score (% or x/24).**	**Key summary measure(s), key finding(s).**
Martin 1995, USA, USD, 6 years.	RYGBP.	Morbid obesity BMI>40	Single treatment centre database, patient bills.	Very low calorie diet.	201 surgical, 161 Medical.	Yes.	No.	No.	Not stated.	Not included, BC not included.	Retrospective, observational, changes in BMI, direct medical costs hospital charges, pathology, radiology, surgeon, anaesthetics, diet, weekly behaviour therapy, partial economic evaluation.	CCA, low. 55%	Cost/pound weight loss. First large-scale comparison of surgical versus medical intervention. Year 6: medical $1500/lb, surgical $750/lb.
Narbro 1999,, Sweden, 5 years.	GB, VBG, GBP.	Age 37-60, men BMI ≥38, women BMI ≥34.	Swedish national insurance.	No surgery.	369 Surgical, 371 matched control.	No.	Yes.	No.	Not stated.	Included, BC not included.	SOS cohort (first 740 consecutive cases), weight lost in kg, adjusted mean number of days of sick leave and disability pension, partial economic evaluation.	CCA, medium 60%	Changes in sick leave and disability pension. Surgical treatment results in a decrease in sick leave and disability pension rates in participants aged 47-60.
van Gemert 1999, Netherlands, USD, lifetime, DR=5%.	VBG.	Morbid obesity BMI>40.	Single treatment centre database, patient interviews, Institute of Public Health.	No surgery.	21.	Yes.	Yes.	Yes. NHP I and II and VAS	Societal.	Included, BC not included.	Model: decision tree, QoL scores, weight loss (kg) and BMI, direct costs of surgical treatment, revisional surgery, medical appointments, diagnostic tests, hospital costs, indirect costs of productivity losses, partial and full economic evaluation.	COI, CUA, medium. 15/24	Cost/QALY. $4,004 to $3,928/QALY. Cost-effectiveness more dominant when productivity gains included.
Agren 2002, Sweden, (1996 USD), 6 years.	GB, VBG, GBP.	Age 37-60, men BMI ≥38, women BMI ≥34.	Swedish hospital data register.	CT.	481 surgical, 481 matched	Yes.	No.	No.	Not stated.	Included, BC included.	SOS cohort (first 962 consecutive cases), average weight reduction, cost of in-patient care as average cost	CCA, medium. 60%	Mean inpatient care costs. TC (discounted) over 6 years surgical: $9,533±10,156, control $2,540±6,113. Average weight reductions of 16% will not reduce hospitalisation costs over

DR=3%.					Control.						per day, partial economic evaluation.		6 years. A substantial share of costs is because of secondary plastic surgery.
Craig 2002, USA, (2001 USD), lifetime, DR=3%.	GB.	Age 35-55, BMI 40-50, non-smokers without CVD, major psychiatric disorders.	Healthcare cost and utilization project database.	No surgery.	NA	Yes.	No.	Yes. Model	Health care system/ third party payer	Included, abdom-inoplasty included.	Model: deterministic decision model, lifetime with reduced BMI, direct medical costs, surgery, follow-up care, treatment of complications, treatment of obesity related diseases, full economic evaluation.	CEA, CUA, high. 21/24	Cost/LY and Cost/QALY. GBP cost-effective. At age 55 years for BMI 40 (kg/m^2) Cost/LY men \$100,200; women \$248,500; Cost/QALY men \$35,600; women \$16,100 and for BMI 50 (kg/m^2) Cost/LY men \$30,700; women \$38900; Cost/QALY men \$13,300; women \$5,400.
Narbro 2002 Sweden, SEK and (2001 EURO), 6 years.	GB, VBG, GBP.	Age 37-60 years, men BMI $\geq$38, women BMI $\geq$34.	Question-naires regarding prescribed medication use.	CT.	510 surgical, 455 Medical.	Yes meds.	No.	No.	Not stated.	Not included, BC not included.	SOS cohort (first 1294 consecutive cases, only patients with complete 6 year follow up included), average weight loss of 16% in 6 years, medication costs for DM, CVD, NSAIDs/Pain, PD, anaemia, GID and other, partial economic evaluation.	CCA, high. 80%	Average annual medication costs. Surgical group lower medication costs for DM (69%) and CVD (31%). These savings balanced by increased medication costs for muscle inflammation, rheumatic disorders and pain, gastro-intestinal, anaemia and vitamin deficiency.
Gallagher 2003 USA, USD, 2 years.	RYGBP.	Severely obese (BMI>50) primarily men, mean age 52$\pm$2 years who underwent RYGB.	Veterans affairs medical records, admin database.	Before and after.	25.	Yes.	No.	No.	Health care system/ third party payer	Included, BC included (pannicu-lectomy).	Retrospective, observational, direct medical inpatient and outpatient costs, partial economic evaluation.	CCA, low. 55%	Mean changes in costs. Reduced obesity related expenditures and utilisation of health care resources. Cost of all care excluding peri-operative charges 1 year post surgery \$2,840$\pm$622 per patient. Cost of undertaking RYGBP is offset by reduction of health care costs within the first year of surgery.
Christou 2004 , Canada, (1996 CAD), 5 years.	All types.	Morbidly obese treated with bariatric surgery with 6 matched controls per case.	Single tertiary centre admin database, provincial insurance database.	No surgery.	1035 surgery, 5746 matched control.	Yes.	No.	No.	Not stated.	Included, BC not included.	Retrospective, observational, weight loss as % initial excess weight loss and % initial BMI reduction, direct medical costs for each hospitalisation, physician visit and prescription medication, partial economic evaluation.	CCA, medium. 65%	Mean health care utilisation and total direct costs. Total direct costs surgery \$8813 (2344), control \$11854 (21220). Mean total direct health care costs were significantly higher in the controls for all specific diagnostic categories. Exceptions were costs for digestive disorders where mean cost for bariatric patients was 68% higher than controls.
Gould 2004, [46], USA, (2003 USD), 6 months.	LRYGBP	Severely obese (mean BMI 51$\pm$2) primarily women medication CMs.	Single study centre, bariatric surgery database.	Before and after.	50.	Yes meds.	No.	No.	Not stated.	Not included, BC not included.	Prospective, observational, cost of prescription medication online pharmacy website, partial economic evaluation.	CCA, medium. 60%	CM-related medication expenses and monthly cost-savings. Monthly savings of all medications \$120, DM \$63, HT \$37, hypercholestraemia \$86, GERD \$91, Depression \$0.
Monk 2004, [47], USA, USD, mean 16 months.	RYGBP	Morbidly obese (mean BMI 57) primarily women.	Single centre, hospital and follow up, pharmacy cost data.	Before and after.	64.	Yes meds and CPAP use.	No.	No.	Not stated.	Not included, BC not included.	Retrospective, observational, cost of monthly medications and CPAP equipment, partial economic evaluation.	CCA, low. 50%	Comorbidity medications and medical equipment monthly savings. Monthly savings CPAP equipment \$207, T2DM \$71, HT \$17, GERD \$34, asthma \$20, all CM \$182.
Potteiger	ORYGBP	BMI>40	Single	Before	51.	Yes	No.	No.	Not	Not	Retrospective, observational,	CCA,	Reduction in number and cost of DM and anti-

2004 [48], United States, USD, 14 months.	LRYGBP	with obesity related DM and HT, or BMI>45.	study centre database.	and after.		meds.			stated.	included, BC not included.	prescription costs based on national wholesale pricing, direct hospital costs included clinicians, laboratory, hospital services, partial economic evaluation.	medium. 60%	HT medications. DM average reduction in monthly medication costs of $109 and HT $34 per month. Annualised pharmaceutical saving of $1,736.
Sampalis 2004 [49], Canada, (1996 CAD), 5 years.	RYGBP, VBG.	Morbidly obese (BMI 50±8) treated with bariatric surgery with 6 matched controls per case.	Single tertiary study centre database, provincial health insurance database.	No surgery	1035 surgery, 5746 control.	Yes.	No.	No.	Not stated.	Included, BC not included.	Retrospective, observational, % change in BMI, % change in EWL, direct hospital costs included all hospital charges, laboratory and clinician charges, partial economic evaluation.	CCA, medium. 75%	Net reduction >$5.7 m for hospitalisations per 1,000 patients treated, within 5 years after surgery. Initial costs of surgery can be amortised over 3.5 years. Cost ratio for control: bariatric year 1: 0.29, year 2: 1.43, year 3: 4.28, year 4: 4.47, year 5 5.21.
Snow 2004 [50], USA, USD, 2.5 years.	LRYGBP	Age 55-75, morbidly obese (mean BMI 48) who underwent LRYGB.	Insurance database, patient prescription verified physician/ primary care.	Before and after.	78.	Yes meds.	No.	No.	Not stated.	Not included, BC not included.	Retrospective, observational, medication cost obtained from 3 retail sources and averaged, partial economic evaluation.	CCA, medium. 60%	Change in medication costs. Decrease of 72% in prescription medication costs per patient per month at 2 years. Average annual cost savings for 78 patients $240,566.
Cendán 2005 [51], USA, USD, ICU LOS (mean 27 days).	All types.	Patient subgroup (19%) emergency or elective critical care.	Single tertiary centre, hospital data ICU resources and costs, medical records.	Before and after.	241.	Yes.	No.	No.	Not stated.	Included, BC not included.	Retrospective, observational, direct hospital costs including ICU and/or advanced medical care unit, partial economic evaluation.	CCA, medium. 70%	Costs for critical care admission (emergent and elective) following surgery and costs for each complication cluster (thromboembolic, pulmonary, anastomotic). DVT-PE increased cost of stay from $29,290±55,000 to $93,000±77,700; pulmonary from $17,200±13800 to $69,000±96,300; anastomotic from $27,420 ±43,200 to $56,200±100,700. Approximately 20% require advance care units.
Finkelstein 2005, USA (2004 USD), USD, Time to break even (mean 9.5 and 7.4 years) DR=3%.	All types.	Age 18-64 years, reported working ≥35 hours per week. BMI≥40 or BMI≥35<40 with CMs.	Medical Panel Expenditure Survey, National Health Interview Survey.	No surgery.	20329.	Yes.	Yes.	No.	Health care system/ third party payer	Not included, BC not included.	Model: two part simulation, estimated annual medical costs attributable to obesity for the surgery eligible and surgery ineligible populations and assumed price of the procedure $25,000, full economic evaluation.	CBA, medium. 18/24	Assuming a 75% reduction in obesity attributable costs, time to break even (at 90th percentile of cost distribution) 5 years for medical and work loss costs. Simulations reveal that 5 or more years of follow up are most likely required for surgery to become cost-saving unless the employee bears a significant fraction of the total costs of the procedure.
Jensen 2005, United States, (2004 USD), life course.	GBP.	Base-case morbidly obese white female, age 40, BMI≥40.	Published sources.	Diet/PA for 2 years at age 18 and BMI≥35.	346 surgery 212 Diet/PA	Yes.	Yes.	Yes. Model	Societal.	Included. BC not included.	Model: decision tree, direct medical costs included operating room, nursing, equipment, anaesthesia, pharmaceuticals, diagnostics tests, ORD-related direct medical costs. Complication costs assumed $5,000, full economic evaluation.	CUA, medium. 17/24	Cost/QALY. Base-case $7,126/QALY. GBP at age 40 is cost-effective compared with a diet and exercise based intervention at age 18 among a cohort of obese white females.

Mehrotra 2005, USA, (2001 USD), 10 years.	GBP, GST, other by ICD codes.	Primary diagnosis of morbid obesity and weight loss surgery.	Inpatient hospital discharge data, health department database, Census population estimates.	Increases in charges by payer type.	269.	Yes.	No.	No.	Health care system/ third party payer	Included. BC not included.	Retrospective, observational, charges based on hospital or facility bills for patient care excluded professional fees such as surgeon or anaesthetic fees, partial economic evaluation.	CCA, medium. 70%	Inflation adjusted total charges for weight loss surgery by payer type (Medicare, Medicaid, private insurance, Self-pay). Despite a significant decline in the average length of stay in hospital after surgery, the inflation-adjusted average charge per procedure doubled from $12,006 to $23,629 from 1990/92 to 2000/02.
Ackroyd 2006, France, Germany, UK, EURO, BPD, 5 years, DR=3.5%.	AGB, GBP.	BMI≥35 and T2DM in France, Germany and United Kingdom.	HTA reports and HODaR Cardiff Research Consortium database. Expert opinion.	CT for T2DM.	1000.	Yes.	No.	Yes. EQ-5D	Health care system/ third party payer	Included. BC not included.	Model: decision tree deterministic linear algorithm, combined effectiveness of BMI reduction, T2DM remission and EQ-5D responses, unit costs in all countries based on identification of the main cost-driving inpatient and outpatient health care resources up to 5 years after surgery, full economic evaluation.	CEA, CUA, BIA, high. 23/24	Cost/QALY. Cost/T2DM-free year. Budget impact for 1000 patients. AGB and GBP are cost-effective at 5 year follow-up and cost-saving in Germany and France. Cost-effective in the UK with a moderate budget impact versus CT. Germany GBP: €-2,455/QALY, €-2,208/T2DM free year, AGB: €-1,305/QALY, €-576/T2DM free year; France GBP: €-4,000/QALY, €-2,118/T2DM free year, AGB: € 1,379/QALY, € 609/T2DM free year; UK GBP: £2,599/QALY, £1,376/T2DM free year, AGB: £3,251/QALY, £1,434/T2DM free year.
Gorman 2006 USA, USD, 2 years.	ORYGB, LRYGB.	BMII≥40 and BMI≥35 with certain CMs.	Health plan database and chart review.	Before and after.	19.	Yes.	No.	Yes. SF-12	Health care system/ third party payer	Included. BC discussed but not included.	Prospective, observational, charges paid extrapolated from claims data included unrelated medical visits (e.g. obstetrics), partial economic evaluation.	CCA, low. 55%	Change in mean annual costs. Sample too small to draw definitive conclusions regarding cost reduction. Difference $-1,300 (5,000); *p* = 0.29.
Nguyen 2006, USA, USD, 2 years.	LAGB.	Morbidly obese on medication for at least one or more CM of HT, HLP, GERD, DM.	Single study centre database, medication history from patient and/or physician.	Before and after.	77.	Yes, meds.	No.	No.	Not stated.	Not included. BC not included.	Retrospective, observational, retail medication costs sourced from online pharmacy, partial economic evaluation.	CCA, medium. 65%	Mean monthly medication costs. One month postoperative medication cost saving GERD (81%), DM (69%), HLP (53%) and HTN (43%).
van Mastrigt 2006, The Netherlands, (1999 EURO), 1 year.	VBG, LAGB.	Age 18-60, BMI>40 or BMI35-40 with significant CM. Excluded psychiatric, previous upper abdominal surgery.	RCT, hospital data and cost diaries.	Before and after. LAGB versus VGB	50 VGB 50 LAGB	Yes	Yes	Yes. EQ-5D	Societal	Included. BC not included.	RCT, % EWL at 12 months and utility, costs individual direct medical and non-medical cost use of unpaid help and productivity losses (friction cost method), full economic evaluation.	CEA, CUA, medium. 19/24	Cost/%EWL and Cost/QALY. After one year, costs and QoL of two treatment modalities were found to be equal. €36,834/QALY.
Hawkins 2007 UK, BPD, 6	LRYGBP LAGB	NHS patients.	Survey.	Before and after.	79.	No.	Yes.	No.	Not stated.	Not included.	Retrospective survey regarding paid employment	CCA, medium	Paid work and weekly hours worked. State benefits claimed before and after surgery.

months.										BC not included.	hours, intention to work and state disability benefits, partial economic evaluation.	75%	Average weekly time worked before 30.1 hours, after 35.8 hours (p<0.01). One-quarter decrease in the number of state benefits claimed after surgery.
Wagner 2007, USA, mean 44 months.	RYGBP	Age<65, medically disabled morbidly obese receiving Medicaid.	One study centre, Medicaid recipients.	No surgery.	38 surgery 16 control	No.	Yes.	Yes. SF-36	Not stated.	Not included. BC not included.	Retrospective survey regarding patients who are working and not claiming Medicaid benefits. Mean excess BMI lost, partial economic evaluation.	CCA, medium. 70%	Number and % Medicaid recipients who return to work. 37% Medicaid-funded patients returned to work compared to 6% of patients from the non-surgical control group.
Cremieux 2008, USA, (2005 USD), 6 years, DR=3.07%.	OGBP, OGB, LGBP, LGB.	Morbidly obese, age>18 years.	Privately insured claims database 5 million lives, 31 companies.	No surgery.	3651 surgery 3651 control	Yes.	No.	No.	Health care system/ third party payer	Included. BC not included	Retrospective, observational, CM reduction (BMI data unavailable in insurance claims database), costs direct medical including prescription drug and medical service (inpatient, emergency department, outpatient, office), partial economic evaluation.	ROI, medium. 75%	ROI. Initial investment approximately $26,000 open and $17,000 laparoscopic surgery. Initial investment is returned within 4 years for open surgery and within 2 years for laparoscopic surgery.
Hodo 2008, USA, USD, 1 year.	ORYGBP LRYGBP	Morbidly obese with CMs, continuous enrolment for 12 months.	Managed care organisation database.	Before and after.	605.	Yes.	No.	No.	Not stated.	Not included. BC not included.	Retrospective, observational, Charlston CM index, medication use/costs, health service use/costs included office, inpatient and outpatient visits, emergency room, prescriptions, partial economic evaluation.	CCA, low. 50%	Mean medication use and costs and claims for specific health services. Medication use and costs decreased within 6 months of bariatric surgery. Pharmacy costs decreased 28% in 6 months after surgery. Health services use greatest decrease in claims (47%) for outpatient visits.
Salem 2008, USA, (2004 USD), lifetime, DR=3%.	LAGB LRYGBP	Base-case morbidly obese male and female BMI≥40, age 35 years.	Published and unpublished sources.	No surgery.	NA	Yes.	No.	Yes. Model	Health care system/ third party payer	Included. Abdomi-noplasty included.	Model: deterministic decision analytic, survival and weight loss, direct medical costs, full economic evaluation.	CUA, high. 20/24	Cost/QALY <$25,000 for both procedures. LRYGB and LAGB cost-effective when evaluating the full range of BMI values and estimates for adverse outcomes, weight loss and costs.
Anselmino 2009, Austria Italy, Spain, EURO, 5 years, DR=3.5%.	AGB, GBP.	Patients with BMI ≥35 and T2DM in Austria, Italy and Spain.	Published and unpublished sources.	CT.	1000.	Yes.	No.	Yes EQ-5D	Health care system/ third party payer	Included. BC not included.	Model: decision tree, annual BMI variation and T2DM prevalence variation (medications and complications) up to 5 years after bariatric surgery. Adopted Ackroyd cost methodology, full economic evaluation.	CEA and CUA, medium. 18/24	Cost/QALY, Cost/T2DM free year. Base-case AGB and GBP inpatients with baseline T2DM cost-saving in Italy and Austria and cost-effective in Spain. Worst case €/QALY AGB Austria €-1,680/QALY; Italy €638/QALY; Spain €3,142/QALY. Worst case GBP Austria €-301/QALY; Italy €94/QALY; Spain €4,347/QALY. Worst case €/T2DM-free-year AGB Austria €-741/T2DM-free-year; Italy €281/ T2DM-free-year; Spain €1,390/ T2DM-free-year. Worst case GBP Austria €-159/T2DM-free-year; Italy €50/ T2DM-free-year; Spain €2,302/ T2DM-free-year.
Ikramuddin 2009, USA,	RYGBP.	Severely obese with	Single academic	Standard care.	2223	Yes.	No.	Yes. EQ-5D	Health care	Included. BC not	Model: CORE Diabetes model (Markov structure)	CEA, CUA,	Cost/QALY. Cost/LY gained. $21,973/QALY and $29,676 LY gained. RYGBP cost-effective

(2007 USD), 35 years, DR=3%.		T2DM, matched cohort.	medical centre, published and unpublished sources.		567 (T2DM or pre-diabetes)				system/ third party payer	included.	used Monte Carlo simulation and tracker clinical endpoints included, BMI, HbA1c, lipids, SBP and medication use, direct medical costs from published sources, full economic evaluation.	high. 20/24	in the treatment of T2DM. Sensitivity analyses indicated surgery is not cost-effective over shorter time horizons, or if the negative quality of life impacts of increased BMI is ignored.
Keating 2009, Australia, (2006 AUD), 2 years.	LAGB.	Class I and II (BMI>30 and <40) recently diagnosed <2 years T2DM.	RCT: resource use trial data and medical records. Unit costs private hospitals, specialists, MBS and PBS.	CT.	30 surgery 30 control	Yes.	No.	No.	Health care system/ third party payer	Included. BC not included.	RCT: within trial efficacy results included remission of diabetes, within trial intervention costs included LAGB surgery costs, mitigation of complications, outpatient medical, medical investigations, pathology, weight loss therapies and medication, full economic evaluation.	CEA, high. 22/24	Within trial cost efficacy cost/case of T2DM remitted. Time horizon of 2 years an additional $16,600 of direct health care investment is required to remit an additional case of recently diagnosed T2DM through LAGB. CT $25,000/case of T2DM remitted.
Keating 2009, Australia, (2005 AUD), lifetime (or age 99 years), DR=3%.	LAGB.	Class I and II (BMI>30 and <40) recently diagnosed <2 years T2DM.	Published within trial RCT cost and efficacy data. Other published sources including MBS and PBS.	CT.	30 surgery 30 control	Yes.	No.	Yes. EQ-5D	Health care system/ third party payer	Included. BC not included.	Model: builds on a within trial CEA by extrapolating cost and outcomes. Markov model that is representative of the natural history of T2DM, mean annual health care costs for people with T2DM, full economic evaluation.	CEA, CUA, high. 24/24	Cost/LY gained. Cost/QALY. Mean healthcare saving of $2,400 and 1.2 additional QALY's per patient. Surgery dominant intervention for managing recently diagnosed T2DM in class I/II obese patients in Australia.
Ananthap-avan 2010, Australia, AUD, lifetime, DR=3%.	LAGB.	Severely obese (BMI≥35) privately insured adolescents (age 14-19 years).	Medical records for resource use and published sources for unit costs.	Standard care.	Data from 28 adolesc-ents modeled for 4120 severely obese.	Yes.	Yes.	No.	Societal.	Included. BC not included.	Model: Markov, change in BMI, direct medical resource use of 28 patients and extrapolated for eligible population, time spent by both parents for travel and consultation accompanying their adolescent, cost offsets using disease costs estimates, full economic evaluation.	CEA, CUA, high. 21/24	Cost/DALY saved. Cost/BMI unit saved. Cost $130 million resulted in incremental savings of 55,400 BMI units at 3 years after surgery. $4,400/DALY. LAGB cost-effective for adolescents.
Campbell 2010, USA, (2006 USD), lifetime, DR=3%.	LAGB, LRYGB.	Morbidly obese adults aged 18-74 years BMI≥35 with CMs or BMI≥40.	Published sources supple-mented by clinical expert opinion.	No surgery.	NA	Yes.	No.	Yes. EQ-5D	Health care system/ third party payer.	Included. BC not included.	Model: Markov, cumulative change in BMI, direct medical inpatient and outpatient costs, full economic evaluation.	CEA, CUA, high. 23/24	Cost/QALY. Cost/LY saved. Both LAGB and LRYGB versus no treatment <$25,000/QALY gained but highly sensitive to model assumptions. ICERs lower for individuals with higher initial BMIs and higher for older individuals. ICERs for men generally higher than for women.
Hoerger 2010, USA, (2005 USD), lifetime (or 95 years),	GBP, GB.	Severely obese adults BMI≥35 with newly diagnosed	National Health and Nutrition Examin-ation	No surgery.	NA	Yes.	No.	Yes. Model	Not stated.	Included. Abdomi-noplasty included.	Model: simulation - expanded Centres for Disease Control and Prevention-RTI Diabetes Cost-Effectiveness Model to incorporate bariatric surgery,	CUA, high. 22/24	Cost/QALY, Cost/case of T2DM remitted. Newly diagnosed T2DM: bypass surgery $7,000/QALY, banding surgery $11,000/QALY. Established diabetes: bypass surgery $12,000/QALY, banding surgery

DR=3%.		or established DM.	Survey and published sources.								diabetes remission and improvement along micro (nephropathy, neuropathy and retinopathy) and macro vascular (CHD and stroke) pathways, direct costs of newly diagnosed and established T2DM, full economic evaluation.		$13,000/QALY. Relative to the newly diagnosed diabetic population, bariatric surgery led to fewer life-years gained and higher incremental cost-effectiveness ratios within the established diabetic population.
Maciejewski 2010, USA, (2006 USD), 6 years.	All types.	Morbidly obese mostly high risk older males (veterans).	Multisite Veterans Affairs Medical Centres.	No surgery	846.	Yes.	No.	No.	Health care system/ third party payer.	Included. BC not included.	Retrospective, observational, costs inpatient and outpatient healthcare utilization and expenditures (including medications), partial economic evaluation.	CCA, medium. 80%	Mean inpatient, outpatient and total costs. Unadjusted inpatient expenditures averaged $1,805 per person 3 years before surgery, increased to $27,536 in the surgical year, and declined in the years after surgery (mean $5,538 1 year after surgery and $2,374 3 years after surgery; unadjusted average outpatient expenditures $985 3 years before surgery, $3,050 in the surgical year, $1,865 1 year after surgery, $1,203 3 years after surgery). Average overall expenditures $6,029 3 years prior to surgery, $36,176 in the surgical year, $11,893 1 year after surgery, $6,787 3 years after surgery.
Makary 2010, USA, USD, 3.5 years.	All types.	Aged 18-64 years, with T2DM who underwent bariatric surgery.	Large insurance database across 7 states.	Before and after.	2235.	Yes.	No.	No.	Not stated.	Not included. BC not included.	Retrospective, observational, use of diabetes medications at specified post-operative time points, total direct health care costs defined as total payout by the insurer for health care claims included hospitalisations, procedures, medications, outpatient visits, consultations and other, partial economic evaluation.	CCA, medium. 65%	Changes in median annualised costs per patient. Baseline average cost per patient $6,376, total annual healthcare costs in the first 3 years after surgery increased by 9.7% ($616) in year 1, decreased by 34.2% ($2,179) in year 2 and decreased by 70.5% ($4,498) in year 3. Metformin greatest medication decrease with 52.9% taking metformin 3 months before surgery and 8.4% taking it 1 year after surgery.
McEwen 2010, USA, USD, 2 years and lifetime. DR=3%.	ORYGBP LRYGBP	Morbidly obese adults who underwent bariatric surgery.	Claims single managed health care plan, seven bariatric centres of excellence, post-operative survey data.	Standard care.	221.	Yes.	Yes.	Yes EQ-5D	Health care system/ third party payer.	Included. BC included.	Model: simulation, change in BMI, change in utility (preoperative quality of life assessed postoperatively), total direct medical costs subdivided into 7 mutually exclusive categories outpatient pharmacy, inpatient, outpatient clinic, diagnostic testing, laboratory testing, emergency room, and other, full economic evaluation.	CUA, medium. 18/24	Cost/QALY. At 2 years $49,000/QALY gained. Over lifetime $1,400/QALY gained. Long term cost-effectiveness appears to depend on the natural history and cost of late postsurgical complications and the natural history and cost of untreated morbid obesity.
Mullen 2010, USA, (2007 USD), 85 months.	ORYGBP LRYGBP		Claims and membership enrolment metro-	No surgery.	224.	Yes.	No.	No.	Health care system/ third	Included: DRG not specific to	Retrospective, observational, change in BMI, costs all hospital, outpatient services, professional services and	CCA, medium. 70%	Comparison of average annual costs. RYGB breakeven point for surgery 3.5 years and surgery cohort used fewer healthcare resources after surgery.

			politan health plan.						party payer.	bariatric surgery. BC not included.	pharmacy charges, partial economic evaluation.		
Perryman 2010, USA, (2008 USD), 2.5 years. DR=4%.	LAGB.	Age>18 years and bariatric surgical eligibility criteria: BMI≥35 with CMs and BMI≥40.	Employees' retirement system database, published sources.	No surgery.	14,100.	Yes.	Yes.	No.	Health care system/ third party payer. Societal.	Included. BC not included.	Model: dynamic input-output, theoretical candidates for LAGB calculated based on national data and eligibility criteria for LAGB, direct health costs and related absenteeism, impacts comprise the costs and benefits of direct, indirect and induced economic impacts, full economic evaluation.	CBA, ROI, medium. 18/23	Payback period and average annual ROI. Economic impact assessment. Payback period 23-24 months from the payer perspective, employer perspective 17-19 months. From a societal perspective the impact on total business activity for Texas (over 5 years) included gains of $195.3 million in total expenditures, $93.8 million in gross product, and 1,354 person-years of employment.
Roger-Anderson 2010, Norway, 2 years.	DS.	Age 18-60, Morbidly obese (BMI BMI≥35 with CMs or BMI≥40) accepted for DS at single study centre.	Self-report of paid workforce particip-ation.	Before and after.	51.	No.	Yes.	Yes SF36	Not stated.	Not included. BC included (pannicu-lectomy).	Prospective self-report of paid workforce participation, % excess BMI loss, paid work on scale 0-100% where 100% is full-time work (37.5 hours per week), partial economic evaluation.	CCA medium. 70%	Hours of paid work per week. Number of patients who performed paid work was unchanged year 0 to year 1. Increased from 54.9% at year 0 to 66.7% at year 2. Percentage of the patients performing paid work at year 2 was lower than the population norm (82%).
Chang 2011, USA, (2010 USD), lifetime, DR=3%.	All types	BMI≥35, two groups with/without ORD.	National Health and Nutrition Examin-ation Survey, published sources.	No surgery.	NA	Yes.	No.	Yes BQL	Health care system/ third party payer.	Included. BC not included.	Model: Mixed Proportional Hazards model and simulation, costs from published studies included average costs without revision, average costs of medical complication and reoperation and perioperative death, and relationship between BMI and associated costs of ORDs, full economic evaluation.	CEA, CUA, high. 22/24	Cost/LY and Cost/QALY. For BMI≥35 <$4,000/QALY, Cost-saving for super obese (BMI≥50) with obesity related CMs. Sensitivity analysis BMI 30-35 found that ICER increases $350/QALY gained for non-ORD group and $500/QALY gained for the ORD group. Sensitivity analysis found that costs-effectiveness analyses are particularly sensitive to cost data.
Clough 2011, Australia, 25.5 months.	LAGB.	Bariatric surgery patients age>60 years, mean BMI 42.2.	Single surgeon's clinic/ hospital records, LapBase database.	Before and after.	113.	Yes meds	No.	Yes SF36	Not stated.	Included. BC not included.	Retrospective, observational, change in medication use for comorbidities including diabetes, HT, sleep apnoea, hyperlipidaemia, reflux, asthma/COAD partial economic evaluation.	CCA, medium. 70%	Mean medication use at baseline, significant average medication reduction (diabetes, HT, sleep apnoea, hyperlipidaemia, reflux, asthma/COAD) was not shown in this study. Marked improvement in QoL after LAGB surgery in the obese elderly was the key positive finding.
Cremieux 2011, USA, (2010 USD), 124 months.	GBP, RYGBP, LAGBP.	Age 18-64 years, BMI≥35, DM.	Admini-strative claims database, 13.5 million lives, 58 companies.	No surgery.	2059 surgery 2059 control	Yes.	No.	No.	Health care system/ third party payer.	Not included. BC not included.	Retrospective, observational, medication utilisation, total direct healthcare costs and medication claims, investment in bariatric surgery is the sum of all incremental costs incurred in	ROI, medium. 75%	ROI. Updated analysis confirms that on average cost savings begin to accrue to third party payers at 3 months after surgery for T2DM patients. Surgery costs were fully recovered at 47 months (95% CI 34-61) for laparoscopic surgeries.

											the month before, the month of and the month after surgery, relative to the total healthcare costs of control patients, partial economic evaluation.		
Ewing 2011, USA, (2008 USD), DR=3,5,10%.	LGBP, LAGB.	Bariatric surgery patients from a single site.	Admini-strative hospital data from single site, published sources.	No surgery.	150.	Yes.	Yes.	No.	Societal.	Not included. BC not included.	Model: input-output model of a regional economy, ongoing improvements in worker productivity, costs expressed in terms of lost output, labour income, employment, and indirect business taxes, full economic evaluation.	CBA, medium. 17/24	Net Present Value. Net benefit $1.3 (DR=10%) to $9.9 B (DR=3%) USD to a regional economy. Net benefit consists of upfront costs of surgical treatment and ongoing gains from improvements in worker productivity.
Finkelstein 2011, USA, (2008 USD), USD, 5.7 years.	LAGB.	Age 18-64 years and diabetes subsample. LAGB mean BMI=44.5, comparison sample mean BMI=44.8.	Admini-strative claims database.	No surgery.	7,310 surgery 7,310 control	Yes.	No.	No.	Health care system/ third party payer.	Included. BC not included.	Retrospective, observational, Cost quarterly payments of total, inpatient (both facility and physician), non-inpatient including hospital, outpatient, physician office, emergency department), and prescription medication claims, partial economic evaluation.	ROI, medium. 75%	Breakeven time horizon for LAGB sample and diabetes subsample. Initial payments for LAGB were fully recovered within 4 years and in just over 2 years for the diabetes subsample.
Finkelstein 2011, United States, USD, 5 years.	LAGB.	Age 18-64 years, DM subsample.	Medical Expenditure Panel Survey and National Health and Wellness Survey, published sources.	No surgery.	2298.	Yes.	Yes.	No.	Not stated.	Included. BC not included.	Retrospective observational, estimation of elasticities for absenteeism, presenteeism, direct medical costs, absenteeism costs and presenteeism costs, partial economic evaluation.	ROI, medium. 75%	Time to breakeven for LAGB sample and diabetes subsample. Inclusion of indirect costs does not substantially change the breakeven period from 2 years found in previous study. Beyond the breakeven period there are additional indirect cost savings that accrue to employers. After 5 years net savings increase from \$26,570(±\$9,000) to \$34,000(±\$10,380).
Kelles 2011, Brazil (2005 USD), 2 years.	RYGBP.	Morbidly obese patients who underwent bariatric surgery, mean BMI=43.	HMO database.	Before and after.	382.	Yes.	No.	No.	Health care system/ third party payer.	Included. BC not included.	Retrospective observational, direct medical costs, partial average cost calculated as total cost minus costs 3 months before and after surgery, partial economic evaluation.	CCA, medium. 65%	Mean cost of surgery and mean total cost of healthcare services per patient. Partial average cost almost doubled after the operation (\$392 versus \$678). Patients presenting with HT, DM, BMI≥50 and aged >50 years have significantly higher costs than patients without these conditions.
Klein et al 2011, USA, (2007 USD), 90 months, DR=3.4%.	All types.	Aged 18-65 years, BMI≥35, DM.	Admini-strative claims covering 8.5 million lives 40 companies.	No surgery.	808 surgery 808 control	Yes.	No.	No.	Health care system/ third party payer.	Not included. BC not included.	Retrospective, observational, 3 outcome measures diagnostic claims for diabetes, claims for diabetes medication, average total costs of diabetes medication and supplies, costs direct medical including medication	ROI, high. 80%	ROI. Therapeutic benefits of bariatric surgery on diabetes translate into considerable economic benefits. Surgery costs were recovered at 30 months (for open and laparoscopic surgeries).

											costs, partial economic evaluation.		
Maklin 2011, Finland, (2010 EURO), 10 years, DR=3%.	GBP, SG, GB.	Morbidly obese with higher prevalence of T2DM.	Admini-strative hospital data, expert opinion of surgeons, population health survey, published sources	Standard care.	NA	Yes.	No.	Yes 15D	Health care system/ third party payer.	Included. Abdomi-noplasy included.	Model: decision tree and Markov model, decline in BMI based on EWL data, T2DM and sleep apnoea, costs based on average costs for each procedure type in the DRG and average annual costs for both treatment groups, excluding cost of medication, full economic evaluation.	CUA, High. 22/24	Cost/QALY. Bariatric surgery cost-effective. Mean costs were €33,870 and €50,495 and mean QALYs 7.63 and 7.05 for bariatric surgery and ordinary treatment respectively. Bariatric surgery dominant in sensitivity analysis. Strong dominance of bariatric surgery over ordinary treatment was removed if BMI at baseline was ≤38.
Bleich 2012, USA, (USD), 6 years.	All types.	Age 18-64 years with T2DM.	Admini-strative insurance data from 7 plans.	Before and after.	6,376.	Yes.	No.	No.	Health care system/ third party payer.	Not included. BC not included.	Retrospective, observational, costs included inpatient, outpatient, pharmacy and other (professional office and professional other), partial economic evaluation.	CCA, Medium. 80%	Means and medians for costs and utilisation measures for individuals with DM before and after surgery. Total mean costs for up to 6 years after having bariatric surgery, individuals with T2DM are more likely to have higher health care expenditures (total mean costs were $9,326 presurgery, $13,400 1 year after surgery, and $13,644 6 years after surgery), are more likely to have hospitalisations but are less likely to have primary care and specialist visits compared with their respective costs and utilization before surgery.
Borg et al 2012, Sweden, SEK, 10 years.	All types.	Overweight and obese from the adult Swedish population BMI>25, age 15-84 years.	Published sources.	Before and after.	NA	Yes.	No.	No.	Health care system/ third party payer.	Included. Costs of follow-up plastic surgery included.	Model: Markov and micro-simulation, changes in BMI, costs attributable risks to obesity related comorbidities, costs inpatient costs, full economic evaluation.	BIA, low. 55%	Comparing no surgery with 3,000 surgeries per year results in a net budget impact of a average of SEK 121 million per annum or SEK 40,000 per patient. This implies that a 55% of the cost of surgery, has been offset by a reduction in the excess treatment costs of obesity related diseases.
Finkelstein 2012, United States, USD, 5 years.	LAGB.	Age 18-64 years. DM subsample.	Medical Expenditure Panel Survey and National Health and Wellness Survey. Published sources.	No Surgery.	2,298.	Yes.	Yes.	No.	Not stated .	Included. BC not included.	Retrospective, observational, estimation of elasticities for absenteeism presenteeism direct medical costs, cost estimates for absenteeism and preseneteesim, partial economic evaluation.	ROI, medium. 80%	Time to breakeven and 5 year net costs of LAGB. Using all three cost categories (medical expenditures, absenteeism and presenteeism), the time to breakeven is reduced from 16 to 14 quarters (6 months). Beyond the breakeven period estimated savings are much larger when indirect costs are considered.
Ghiassi 2012, USA, USD, 1 year.	RYGBP	Morbidly obese with DM and HT who had undergone RYGBP and	Medical records of consecutive patients at a single site – Veteran's	Before and after.	106.	Yes meds	No.	No.	Health care system/ third party payer.	Not included. BC not included.	Retrospective, observational, progression, improvement, or remission of DM or HT was determined at 1 year after surgery and %EWL, costs current Veterans Affairs	CCA, medium 70%.	Mean annual costs meds. The annual costs of medications to treat HT was reduced by 65% at 1 year of surgery and 88% for DM. In a subset of patients with persistent HT of DM after surgery, cost reduction 58% for HT and 69% for DM.

		taking DM and HT meds. Mean BMI=47. Mainly male cohort.	Affairs health care system.								pharmacy subsidised cost for each medication, partial economic evaluation.		
Gripeteg 2012, Sweden, 20 years.	GB, GBP, VBG.	SOS cohort: Age 37-60 years, men BMI≥38, women BMI≥34.	Swedish Social Insurance Agency.	Standard Care.	2901.	No.	Yes.	No.	Not stated.	Not included. BC not included.	SOS cohort, % weight change, incidence and number of disability pension days, partial economic analysis.	CCA, medium 75%	Incidence of disability pension and number of disability pension days over 10 years. Bariatric surgery may be associated with favourable effects on disability pension for up to 19 years in men whereas neither favourable nor unfavourable effects could be detected in women.
Maciejewski 2012, USA, USD, 6 years.	RYGBP.	Morbidly obese mainly high risk older male patients (veterans).	Multisite VAMCs.	No surgery.	847 surgery 847 control	Yes.	No.	No.	Health care system/ third party payer.	Included. BC not included.	Retrospective, observational, costs total veterans affairs expenditure sum of inpatient and outpatient expenditures, partial economic evaluation.	CCA high 85%	Mean inpatient, outpatient and total costs. Adjusted total expenditures converged in the 3 years after surgery, from $4,397 higher in the first 6 postsurgical months to similar expenditures in the 31 to 36 postsurgical months. Bariatric surgery was not associated with reduced expenditures in this cohort of older, predominantly male patients 3 years after the procedure.
Michaud 2012, USA, (2010 USD), 46 years DR=3%.	Focus on RYGBP.	Age 50 years, BMI>40 or BMI35-40 with qualifying CMs and BMI 30-35 with qualifying pre-existing conditions – DM.	Published sources.	No surgery.	NA	Yes.	Yes.	No.	Societal.	Included. BC not included.	Model: Future Elderly Model (micro-simulation model), % weight loss, health care costs (private, Medicare and Medicaid); tax revenue; social security expenditures (disability and old-age pensions), full economic evaluation.	CEA high 24/24	Net present value per capita amongst eligible patients. Cost/LY gained. Present value of total medical costs for people who have had bariatric surgery is reduced by $4,649: $3,247 accrues to Medicare, $276 to Medicaid and $1,126 to other (private) sources. On balance, bariatric surgery generates substantial private value for those treated. Net public fiscal effects are modest, primarily because the size of the population eligible for treatment is small. Net social effect is large once improvements in life expectancy are assumed.
Myers 2012 USA, USD, 8 years.	LRYGBP	Severely obese BMI 40-60, aged 35-60 years. Single site and single surgeon.	State managed health insurance agency.	No surgery.	39 surgery 911 no surgery	Yes.	No.	No.	Health care system/ third party payer.	Included. BC not included.	Retrospective, observational, % EWL, medical costs included all medical claims (office visits, ED, laboratory/pathology, physical and occupational therapy, sleep facilities and remaining) except pharmacy claims. Pharmacy costs included direct pharmaceutical expenditure, partial economic evaluation.	CCA, high. 85%	Changes in mean medical and pharmacy costs per person per year. Combining total costs across the eight years of the study total medical costs for the non-surgical group were $73,212. The surgical group’s costs were $77,894, which included the $25,000 cost of the surgery. Surgery costs may begin to be recouped within the first 4 years after surgery with continued effects 6 years after surgery.
Neovius 2012, Sweden, (2011 USD),	GB, GBP, VBG.	SOS cohort: Age 37-60 years, men	National Patient Register	CT.	2,010 surgery 2,037	Yes meds.	No.	No.	Not stated.	Included. BC not included.	SOS study, % weight loss, hospitalisation frequency, hospital days by year and	CCA, high. 90%	Health care use and medication cost. Surgically treated patients used more inpatient and non-primary outpatient care during the

20 years.		BMI ≥38, women BMI ≥34.	and Prescribed Drug Register		control						non-primary outpatient care, partial economic evaluation.		first 6 year period after undergoing bariatric surgery but not thereafter. Drug costs from years 7 to 20 were lower for surgery patients than for controls. From year 7 to year 20, the surgery group incurred a mean annual drug cost of $930; control patients $1,123.
Sussenbach, 2012, Brazil, (2011 USD), 3 years.	RYGBP	Bariatric surgery patients with T2DM, SAH and dyslipid-aemia.	Single study centre medical charts.	Before and after.	194.	Yes.	No.	No.	Health care system/ third party payer.	Not included. BC not included.	Retrospective, observational, improvement or resolution of CMs (three groups), costs excluded costs of the surgery, preoperative costs followed the recommendations of standardised guidelines for each CM, postoperative costs calculated according to information on medical charts e.g. doctors visits, examinations and tests and medications, partial economic evaluation.	CCA, medium. 70%	Annual costs before and after surgery. Annual median expenses for medications, professional care and examinations in the preoperative period were $1,706, In the postoperative period these expenses were $1,174 in the first 12 months, $713 for 13-24 months and $431 for 25 to 36 months.
Zanela 2012, Mexico, (2011 PESO), 10 years, DR=4.5%.	All types.	Adults, class II obese (BMI≥35), at least one CM, previous failed CT.	Mexican Social Security Institute DRG list. Mexican National Institute of Public Health.	No surgery.	150 surgery 150 control	Yes.	No.	No.	Health care system/ third party payer.	Not included. BC not included.	Model: discrete event simulation, comorbidity resolution at a different rate over time (resolution and re-incidence of T2DM, HT and hypercholesterolemia), costs inpatient, outpatient, pharmacy partial economic evaluation.	ROI, high. 90%	ROI time or cost of breakeven point 6.8 years. Total costs for the surgical group were 52% less than conventional treatment group after 10 years. Bariatric surgery reduced the cost of treating T2DM, HT, and hypercholesterolemia by 59%, 53%, and 65%, respectively. ROI for bariatric surgery in patients with T2DM as the only comorbidity was 4.4 years.
Faria 2013, Global/Portug al, EURO, lifetime, DR=3%.	GB, GBP.	Morbidly obese with and without CMs, Baseline mean BMI=46.9.	Administ-rative hospital data and published sources.	CT.	NA	Yes.	Yes	Yes.	Societal.	Included. BC not included.	Model: Markov, weight loss and control of comorbidities, societal costs extracted from published sources and an institutional database, full economic evaluation.	CUA, medium. 19/24	Cost/QALY. Compared to the best medical management, in the global population of patients with a BMI of >35 kg/m2, surgery rendered 1.9 extra QALYs and saves on average €13,244 per patient. Younger patients, patients BMI 40-50 kg/m², and patients without ORD derive greater benefit.
Finkelstein 2013, USA, USD, 10 years,	LAGB LRYGB	Morbidly obese who underwent bariatric surgery and DM subsample.	Insurance claims database	No surgery	9,631 surgery; 9,639 No surgery – MO code sample; DM 2,447.	Yes	No	No	Not stated	Included. BC not included.	Retrospective, observational, Costs person-specific quarterly payments of total, impatient (facility and physician), non-inpatient (including payments for hospital outpatient, physician's office visits, and ED), and prescription drug claims, partial economic evaluation.	ROI medium. 80%	Time to breakeven and net costs. Net costs and time to breakeven resulting from bariatric surgery are less favourable than has been reported in prior studies. Even with a more conservative and likely more accurate comparison sample, the business case for LAGB appears favourable. Without the morbid obesity code comparison sample, time to breakeven for LAGB increases to 5.25 years with a 5 year net cost of $690.
Karim 2013, UK, 2 years.	LAGB	Obese adults BMI≥35,	Single site hospital database.	Before and after.	73.	Yes.	No.	No.	Not stated.	Included. BC not included	Retrospective, observational, utilisation and costs hospital admissions, outpatient	CCA, medium. 70%	Changes in utilisation of hospital services and associated costs. Total estimated costs savings ranged between $32,593 and $41,177 per

		age 18-65 years who underwent LAGB.	Individual case notes.								clinics, medications (DM, HT and analgesia), partial economic evaluation.		annum.
Karim 2013, UK, GBP, 2 years.	LAGB, LRYGB, LSG.	Morbidly obese patients age 25-65 years who underwent bariatric surgery.	Single site hospital medical records and patients' GPs.	Before and after.	88.	Yes.	No.	No.	Not stated .	Included. BC not included.	Retrospective, observational, costs hospital inpatient, outpatient clinic and meds, partial economic evaluation.	CCA, medium. 70%	Summary of annual cost savings. Total annual cost savings ₤30,404. Annual cost savings medications ₤11,452, hospital admissions ₤16,420 and ₤2,532 outpatient clinics.
Keating 2013, Australia (2009 AUD), 4 years.	LAGB.	Population of Australians undergoing LAGB in 2007.	Australian government Medicare database.	Before and after.	9,542.	Yes meds.	No.	No.	Health care system/ third party payer	Not included. BC not included.	Retrospective, observational, costs pharmaceutical data classified into 8 therapeutic categories. Unit costs paid by Medicare, partial economic evaluation.	CCA, high. 90%	Mean annual costs per person for prescription medication. Net reduction in pharmaceutical utilisation from 10.5 to 9.6 pharmaceuticals prescribed per person/year, and costs decreased from $517 to $435.
Lam 2013, USA, USD, 1 year.	LRYGBP	Morbidly obese Native Hawaiians who underwent LRYGB.	Medical records from single site.	Before and after.	50.	Yes meds.	No.	No.	Health care system/ third party payer.	Not included. BC not included.	Retrospective, observational, successful weight loss >50% excess body weight lost at one year postoperatively, costs medications from online pharmacy for 30 day supply of prescription medications, partial economic evaluation.	CCA, Medium 70%.	Average monthly and annual cost changes of prescription medications. Average number of prescription medications decreased from 3.5 per patient preoperatively to 1.1/patient at one year, monthly cost saving $196.
Lee 2013, Australia, (2003 AUD), lifetime, DR=3%.	LAGB	Population study: morbidly obese Australians BMI>35 and BMI>40	Published sources.	No surgery.	NA	Yes.	Yes.	No.	Health care system/ third party payer Societal.	Included. BC not included.	Model: Markov, costs intervention costs from previous published studies, time and travel costs 25% of hourly wage rate and disease costs, full economic evaluation.	CEA, high. 23/24	Cost/DALY averted. For BMI>35 $2,154/DALY averted. LAGB cost-saving when provided to all individuals with BMI>40. Cost-effective when extended to all individuals with BMI>35, but at a substantial aggregate cost. Results highly sensitive to changes in the likelihood of long-term complications.
Pollock 2013, UK, BPD, 5 years.	LAGB.	Morbidly obese patients with newly diagnosed <2 years T2DM.	RCT data. Published sources.	Standard care.	100 surgery 100 no surgery	Yes	No	No	Health care system/ third party payer.	Included. Abdomi-noplasty included.	Model: budget impact model, reduction in BMI, HbA1c and SBP, costs inpatient, outpatient and medications, partial economic evaluation.	CCA, medium 80%	Cost savings of ₤913 per patient for LAGB over 5 years compared with standard medical management for newly diagnosed T2DM.
Pollock 2013, UK, (2010 BPD), 40 years, DR=3.5%	LAGB	BMI = 30-40, recently diagnosed T2DM.	RCT data. Published sources	Standard care.	1000.	Yes.	No.	Yes.	Health care system/ third party payer.	Included. BC not included.	Model: CORE diabetes and nonparametric bootstrapping, RCT data: glycaemic control at the end of two years, % change HbA1c, weight, SBP and DBP, waist circumference, fasting lipids, costs inpatient, outpatient	CUA, high. 23/24	Cost/QALY. LAGB is a highly cost-effective treatment in obese patients with T2DM in the UK setting compared with standard medical management

											LAGB and diabetes medications and complications, full economic evaluation.		
Song 2013, South Korea, (2011 USD), lifetime, DR=5%.	LAGB LRYGBP LSG	Severely obese Korean adults over 30 with BMI 30≤40 (severe obesity for Asian population BMII≥30)	Hospital adminis-trative, medical charts, survey of bariatric surgeons, National Health Insurance Statistics	No surgery.	NA	Yes.	No.	Yes. EQ-5D	Health care system/ third party payer.	Included. BC not included.	Model: combined decision tree and Markov, change in mean BMI, utility weights, costs inpatient, outpatient and medications, full economic evaluation.	CUA, high. 24/24	Cost/QALY. ICER of bariatric surgery compared with conventional treatment was US$1,771/QALY, suggesting that bariatric surgery was cost-effective in South Korea.
Wang 2013, USA, USD, lifetime, DR=3%.	LRYGBP ORYGBP LAGB	Individuals eligible for bariatric surgery based on BMI≥35. Reference case 53 year old female BMI=44.	Adminis-trative claims database and published sources.	No surgery.	NA	Yes.	No.	Yes. SF- 12 and EQ-5D	Health care system/ third party payer.	Included. BC not included.	Model: decision analytic first 5 years then natural history model, changes in BMI and utility, costs estimated lifetime direct medical costs associated with the three procedures compared with no surgery, full economic evaluation.	CUA high. 23/24	Cost/QALY. $6,600/QALY for LRYGB, $6,200/QALY for LAGB, $17,300/QALY for ORYGB. Bariatric surgery produced additional life expectancy (80-81 years) compared to no surgery (78 years).
Weiner 2013, USA (2005 USD), 6 years.	LAGB, LGBP, OGBP, other restrictive and unknown.	Patients who underwent bariatric surgery, age≥18 years, 1:1 matched.	Health insurance plans.	No surgery.	29,820.	Yes.	No.	No.	Not stated.	Included. BC not included.	Retrospective, observational, costs medical and pharmacy claims data, partial economic evaluation.	CCA high. 95%	Changes in mean costs. Regression adjusted ratios. Total costs were greater in the bariatric surgery group during the second and third years following surgery but were similar in later years. Bariatric surgery group's prescription and office visit costs were lower and their inpatient costs were higher. Surgical group costs years 1 to 6 Y1 $8,905 (18,814), Y2 $9,908 (19,273), Y3 $9,211 (19,263), Y4 $9,051 (19,520), Y5 $9,386 (21,137), Y6 $9,259 (26,909).
Castilla 2014, Spain, (2012 EURO), lifetime, DR=3%.	GBP	Patients who underwent bariatric surgery age 18-55 years.	Spanish NHS, published sources.	No surgery.	79.	Yes.	No.	Yes. SF-36 EQ-5D OP MA II	Health care system/ third party payer.	Not included. BC not included.	Model: discrete event simulation, change in utility, costs direct medical costs from Spanish NHS, full economic evaluation.	CUA, high. 22/24	Surgery group gained 5.63 QALYs. Lifetime savings €13,944. The total cost of the intervention branch is close to half the cost of the non-intervention branch (€17,431 vs €31,425).
Bairdain 2015, United States, USD, 7 years, DR=3%.	LRYGBP	Severely obese adolescents who underwent bariatric surgery.	Children's hospital database.	No surgery.	11.	Yes.	No.	Yes. EQ-5D	Health care system/ third party payer.	Not included. BC not included.	Model: Markov, costs direct medical preoperative, perioperative and postoperative (clinic and ancillary charges), full economic evaluation.	CUA, medium. 16/24	Cost/QALY at year 7 $36,570/QALY. At a WTP threshold of $100,000/QALY, bariatric surgery was not cost effective in the first three years, but became cost-effective after three years ($80,065/QALY in year 4 and $36,570/QALY in year 7).
Borisenko	GBP,		Scanadan-	No	NA	Yes.	No.	Yes.	Health	Included.	Model: Markov, BMI	CUA,	Over a lifetime surgery led to savings of €8408

2015, Sweden, (2012 EURO), lifetime, DR=3%.	SG, GB.		avian obesity surgery registry and published sources.	surgery.				EQ-5D	care system/ third party payer.	BC included.	reduction, CVD, T2DM, complications, utility, costs cost of surgery with and without complications, annual cost T2DM and CVD (e.g. stroke, MI, TIA), full economic evaluation.	high. 23/24	and generated an additional 0.8 LY and 4.1 QALYs per patient. Base-case bariatric surgery cost saving. All four specified diabetic cohorts were cost saving (moderately, severely, morbidly and super obese). Time delay in surgery led to significant losses of clinical benefits (in the range of 0-0.6 LY and 0.2-1.2 QALYs). Losses of clinical benefits higher in males and diabetic patients.
Czernichow 2015, France, EURO, 4 years.	GB 62.5%, GBP, SG.	Obese patients who had undergone primary bariatric surgery.	National claims insurance database.	Before and after.	350.	Yes.	No.	Yes.	Health care system/ third party payer (stated societal)	Included. BC not included.	Retrospective, observational, costs direct costs. All items of health care consumption eligible for reimbursement and associated costs were assessed for each study period at current prices, partial economic evaluation.	CCA, high. 95%	Annual total direct cost per patient before and after bariatric surgery. Annual per capita reimbursed health expenses evolved from €2,633 (±3,124) year (T-2) to €3,755 (±5,037) year (T+2) with differences according to the type of surgery. Most items of medical consumption started to decrease in T+2.
Keating 2015, Sweden, (2013 USD), 15 years.	GB, GBP, VBG.	SOS cohort: Age 37-60 years, men BMI ≥38, women BMI ≥34. Stratified for baseline glucose status.	National prescribed drug register and question-naires. National patient register (inpatient and outpatient).	CT.	4,030 patients 2,836 eugly-cemic 591 pre-diabetes 603 diabetes	Yes.	No.	No.	Not stated.	Included. BC not included.	SOS study, baseline glucose status, costs inpatient, non-primary outpatient and medications, partial economic evaluation.	CCA, high. 100%	Adjusted mean differences for 15 year aggregated drug, outpatient, inpatient, and total healthcare costs. Drug costs were lower in the surgery group for pre-diabetes ($10,194 vs $13,186; –$3,329 [–5,722 to –937]; p=0·007) and diabetes ($14,346 vs $19,511; –$5,487 [–7,925 to –3,049]; p<0·0001) subgroups than in the CT group. Total healthcare costs were higher for patients with euglycaemia or pre-diabetes in the surgery group than in the CT group, but we detected no difference between the surgery and CT groups for patients with diabetes.
Warren 2015, USA, USD, 10 years.	All types	Obese T2DM eligible for bariatric surgery and control group T2DM	American Diabetic Association estimates	No surgery.	Surgery eligible group 1,000 (surgery 200, no surgery 800) control 1,000	Yes.	Yes.	No.	Not stated	Not included. BC not included.	Retrospective, observational, resolution of T2DM, costs direct costs (inpatient and outpatient medical costs) included, indirect costs reduced work productivity and mortality, partial economic evaluation.	CCA, medium. 75%	Total, direct and indirect costs of bariatric surgery. The projected annual costs of T2DM per person is between $1,700 and $2,100. Considering only the direct medical costs of T2DM, the 10 year aggregate cost savings compared with the control group is $2.7 million/1000 patients; the total (direct and indirect) cost savings is $5.4 million/1000 patients.

Table 3A: Characteristics of cost-effectiveness and cost-utility studies that investigated people with diabetes who underwent bariatric surgery versus conventional treatment

Reference, currency study population	DR	Cost of the procedure	Economic metric (cost-effectiveness studies: base case)	Economic metric (cost-utility studies: base case)	Sensitivity analyses
Anselmino 2009, EURO. Study population: AGB and GBP for BMI ≥ 35 and T2DM	3.5%	Base case input - average cost per patient: GBP: Austria: €6,361; Italy: €7,831; Spain: €8,344. AGB: Austria: €4,785; Italy: €7,759; Spain: €5,995.	GBP: Austria: €-740/ T2DM free year; Italy: €-637/ T2DM free year; Spain: €1,362/ T2DM free year. AGB: €/T2DM free year: Austria: €-1,201; Italy: € 452;Spain: €611.	GBP: Austria: €-740/QALY gained; Italy: €-637/gained; Spain: €1,362/gained. AGB: Austria: €-1,201/QALY gained; Italy: €-452/QALY gained; Spain: €611/QALY gained.	Worst case AGB remains cost-saving, GBP breakeven in Austria, Both procedures breakeven in Italy, Both cost-effective in Spain with accepted cost-effectiveness threshold of €30,000/QALY gained.
Ikramuddin 2009, (2007 USD). Study population: RYGBP Mean BMI 48.4 and DM.	3%	Base case input: cost of initial surgery and follow-up: $24,289. Major reoperation (early) $38,960, moderate reoperation (early) $23,851, major reoperation (late) $42,896, moderate reoperation (late) $14,736, any complicated weighted average $14,663.	Base case: $29,676/life-year gained.	Base case: $21,973/QALY gained.	Reduced effects on A1C, exclusion of lipid effects, lower and higher DR (0 and 6%) and lower costs of treatment. ICERs remained under $50,000/QALY gained WTP threshold in most cases. Only when time horizon greatly reduced and QoL impact of increased BMI was excluded ICERs exceeded the threshold.
Keating 2009 (2006 AUD). Study population: RCT LAGB and CT BMI > 30 - < 40 recently diagnosed T2DM.	NA	Mean cost per patient over trial period: Cost of LAGB surgery (private hospital): $8,527. Mitigation of surgical complications (lap-band removal, revisions, port infection) $866.	AUD$16,000/additional case of T2DM remitted. USD$11,840/additional case of T2DM remitted.	NA	No.
Keating 2009, Australia, (2006 AUD). Study population: LAGB with CT BMI > 30 - < 40 recently diagnosed T2DM.	3%	Cost of the procedure based on Keating 2009 within trial costs. Complications unit cost: gastric prolapse $5,758; band erosion $14,691; port infection $2,695; band removal $5,134.	Cost/life-year gained Dominant	Cost/QALY gained Dominant	Worst-case scenarios for the intervention effect and the annual cost of treating T2DM shifted the economic status of surgical therapy from dominant to cost-effective $39,700/QALY gained and $13,400/QALY gained respectively.
Hoerger 2010, United States, (2005 USD). Study population: LAGB and GBP to CT severely obese with newly diagnosed DM and severely obese with established DM.	3%	Surgery and first year of costs: GBP $23,871 ($6,612 – $55,261); LAGB $15,169 ($2,857 – $30,186).	NA	Patients with newly established diabetes: GBP $7,000/QALY gained; LAGB: $11,000/QALY gained Patients with established diabetes: GBP: $12,000/QALY gained; LAGB: $13,000/QALY gained.	Varying surgery costs had a larger impact on GBP than the LAGB ICERs. Varying follow-up costs had a bigger impact on the LAGB than GBP cost-effectiveness ratios. Varying change in BMI from surgery had very little effect but varying the direct QoL improvement per unit of BMI loss from 0.017 to 0 had the biggest impact on cost-effectiveness ratios. All cost-effectiveness ratios were <$40,000/QALY.
Pollock 2013, United Kingdom, (2010 BPD). Study population: LAGB severely obese with DM for mean 1 year SD standard deviation 4 months.	3.5%	Total mean (standard deviation) direct costs of LAGB surgery base case including inpatient, outpatient, costs of complications, revision and reversal: £23,562 (£22,754 – £24,496).	NA	£3,602/QALY gained.	One-way sensitivity analyses DR 0 and 6%, time horizon, unit costs, HbA1c, SBP and BMI benefits base case was broadly insensitive. Worst case scenario revealed a mean outcome that would not be considered cost-effective at WTP threshold of £20,000/QALY Worst case revealed £36,377/QALY gained. Conversely best case revealed dominance.
Borisenko 2015, Sweden, (2012 EURO). Study pop: 16 cohorts of 41 year old non-smoking males and females with BMI group and T2DM. Results on other severe obesity multiple cohorts also considered.	3%	Cost of bariatric surgery without complications €4,915 (39 – 5,898); cost of bariatric surgery with complications €5,766 (4,613 – 6,919).	NA	Bariatric surgery is cost saving in all 4 pre-specified diabetic cohorts (moderately, severely, morbidly and super-obese).	One-way sensitivity analysis for all cohorts showed that four parameters can affect the cost saving effect of surgery (1) the magnitude of the effect of surgery, (2) start age (better to operate patients when they are younger), (3) BMI (better to operate when BMI is lower), and (4) inclusion of an annual visit to a surgeon during the follow-up program from year three and onwards. Change of cost variables with 50 % variations did not influence the cost saving effect of surgery. The most sensitive parameter from cost variables was the annual cost of type 2 diabetes.

Key: AGB, adjustable gastric band; British Pound, BPD; DM, diabetes mellitus; DR, discount rate; EURO, Euro; GBP, gastric bypass; ICER, incremental cost-effectiveness ratio; LAGB, laparoscopic adjustable gastric band; LRYGBP, laparoscopic Roux-en-Y gastric bypass; LSG, laparoscopic sleeve gastrectomy; QALY, quality-adjusted life-years; RYGBP, Roux-en-Y gastric bypass; SG, sleeve gastrectomy; T2DM, type 2 diabetes mellitus; WTP, willingness to pay

Table 3B: Characteristics of cost-effectiveness and cost-utility studies that investigated people with severe/super-obesity who underwent bariatric surgery versus conventional treatment

Reference/currency study population	DR	Cost of the procedure	Economic metric (cost-effectiveness studies – base case)	Economic metric (cost-utility studies base case)	Sensitivity analyses
Campbell 2010, United States, (2006 USD). Study population: BMI ≥ 40 kg/m² and BMI ≥ 35 kg/m² with comorbidities who underwent LAGB and LRYGBP versus no treatment.	3%	Cost of initial surgery and follow-up LAGB \$15,465; LRYGB \$23,157. Cost of early and late major and minor reoperations for both procedures range \$426 to \$41,708.	Aggregate patient population age 40 yrs: LAGB \$9,300/life years saved; LRYGB \$10,200/life years saved Super-obesity BMI >50 kg/m²: female both LAGB and LRYGB dominating; male LAGB \$600/life-years saved; LRYGB \$1,700/life-years saved.	Aggregate patient population age 40 yrs: LAGB \$5,400/QALY gained; LRYGB \$5,600/QALY gained Super-obesity BMI >50 kg/m²: female both LAGB and LRYGB dominating; male LAGB \$400/QALY gained; LRYGB \$1,100/QALY gained.	Alternative sources of efficacy estimates, patients assumed to regain half their cumulative BMI lost after 5 years over the following 5 year period. Multiple one way sensitivity analyses then conducted to changes in efficacy, rates of adverse events and costs. Overall parameter uncertainty tested with regard to treatment efficacy, rates of complications, costs and utilities. Results robust to reasonable variation in model parameters.
McEwen 2010, United States, USD. Study population: Mean BMI 51 kg/m² with co-morbidities LRYGBP and ORYGBP	3%	Average cost for LRYGBP \$10393; average cost for ORYGBP \$11,705.	NA	2 year time horizon \$48,622/QALY gained; lifetime time horizon \$1,425/QALY gained.	Sensitivity analysis for age, sex, race, pre-surgical BMI, diabetes status and type of surgical procedure. Bariatric surgery was cost-effective under most scenarios, but less cost-effective in men, white patients, less obese patients, and when performed as an open procedure.
Chang 2011, United States, (2010 USD). Study population: severely obese with obesity related diseases and without obesity related diseases who underwent bariatric surgery.	3%	Average cost of bariatric surgery \$26,315. Cost of surgical complications \$1,083, cost of early reoperation \$30,074, cost of perioperative death \$46,782.	Obesity related diseases for BMI 35 - 40 kg/m²: \$6,468/life-year saved; without obesity related disease for BMI 35 - 40 kg/m² \$13,249/life-year saved.	Obesity related diseases for BMI 35-40 kg/m²: \$2,413/QALY gained; without obesity related disease for BMI 35-40 kg/m² \$3,872/QALY gained. Obesity related diseases for BMI ≥ 50 kg/m² cost-saving; without obesity related disease for BMI ≥ 50 kg/m² \$1,904/QALY gained.	Direct medical costs for the base-case were derived from one published study. Varying the cost data with data from other published studies yielded changes from base-case. This sensitivity analyses was only reported for people with obesity-related comorbidities. Cost data from one study revealed cost-saving for all incremental cost-effectiveness ratios. Cost data from another study revealed similar results for BMI 35-40 kg/m² and higher pre-surgery BMIs revealed cost-saving.
Maklin 2011, Finland, (2010 EURO). Study population: BMI at baseline 47 kg/m² (range: 38-59 kg/m²), age 43 years, men 35% (range 9-50), LAGB (2%), GBP (68%), SG(30%).	3%	Average costs of procedures: gastric bypass €14,672; SG €14,752; LAGB €13,210.	NA	All surgical procedures showed strong dominance.	Surgery remained dominant when the parameter values for mortality, probability for reoperation, abdominoplasty or co-morbidities, EWL or weight gain after surgery were varied. Increasing the costs of surgery did not remove the dominance. Worst case scenario was evaluated using the most pessimistic parameter values on effectiveness and costs of bariatric surgery. Dominance was also not removed in the worst case scenario. Only variation in BMI at baseline seemed to have an effect on results. Strong dominance of bariatric surgery if BMI set at 38 kg/m².
Michaud 2012, United States, (2010 USD). Study population: a) current eligibility: BMI > 40 kg/m², or BMI 35-40 with qualifying comorbidties; and (b) extended eligibility: BMI > 35 kg/m² and BMI 30-35 kg/m² with qualifying comorbidities RYGBP.	3%	Bariatric surgery (focus on RYGBP) total economic cost which includes treatment cost, additional medical expenditures, deadweight loss minus additional earnings: \$12,666.	Current eligibility: \$8,171/life years gained. Extended eligibility: \$10,579/life-years gained.	NA	For the current eligibility population variation in the effectiveness of bariatric surgery, lowering effectiveness by 10% cuts life expectancy gains by 0.55 years and cost/life years increases \$16,405/life-years. Changing the assumption of permanent weight loss to 50% weight regain cost-effectiveness remains low \$12,318/life-year. The results for bariatric surgery appear to be robust to variation in the effectiveness of treatment.
Faria 2013, Global/Portugal, EURO Study population: severely obese with obesity-related diseases and without obesity-related	3%	Expected cost LAGB €41,056 and GBP €29,254.	NA	Compared with the best medical management , in the global population of patients with a BMI≥35 kg/m², GBP renders 1.9	Stratified for patient subgroups based on age, BMI, T2DM and absence of co-morbidities. Younger patients <40 years cost saving. T2DM dominance of GBP. Patients with the most benefit are those in the

diseases.				extra QALYs and saves on average €13,244 per patient	intermediate weight group BMI 40 50 kg/m². Patients with BMI 30-35 kg/m² GBP cost effective €13,071/QALY gained. For the global population GBP is cost-saving from 8 years onwards.
Lee, 2013 , Australia, (2003 AUD). Study population: LAGB. BMI>35 kg/m² and BMI >40 kg/m².	3%	Cost of initial LAGB surgery cost/person $11,290.	BMI >40 kg/m² dominant (95%CI: dominant – $588). BMI>35 kg/m² $2,154/DALY averted (95%CI: dominant - $6,033).	NA	Altered DR to 0 and 6 %. Increased annual probability for each complication by order of one magnitude. Tested the stable weight loss assumption. Uncertainty analyses to assess the level of parameter uncertainty. The largest observed changes to base case analyses occurred after excluding cost offsets; and increasing the rates of maintenance and complication by order of magnitude results still fell below the WTP threshold $50,000/DALY.
Song 2013, South Korea, (2011 USD). Study population: Asian population severely obese 30 - <40 kg/m² in South Korea.	5%	Cost of initial procedure: LAGB $7,042; LRYGB $13,000 and LSG $9,511.	NA	$1,771/QALY gained	Sensitivity analyses altered discount rates (0% and 3%), costs (two-way), utility weights, time horizon. Bariatric surgery was dominant with 0% and 3% discount rates however when time horizon reduced by 15 years showed the largest change to $17,639/QALY gained.
Wang 2013, United States, USD. Study population: Average individual undergoing bariatric surgery 53 year old female BMI 44 kg/m².	3%	Total cost < 31 days: LRYGBP $16,691; ORYGBP $20,675: LAGB $14,159	NA	LRYGBP $6,000/QALY gained; ORYGBP $17,300/QALY gained; LAGB $6,200/QALY gained.	Results were sensitive to alternative weight change scenarios. For full weight regain 15 years after the procedure LRYGBP $24,100/QALY gained; ORYGBP $59,500/QALY gained; LAGB $26,700/QALY gained. One way sensitivity analysis showed that parameters with the largest impact were BMI at baseline, age at the time of procedure and gender. ICERs higher with men. LAGB cost-saving at baseline BMI of 54 and above. The ICER estimates for bariatric surgery appear to be cost-effective under most modelled scenarios
Castilla 2014, Spain, (2012 EURO). Study population: Average BMI 50.7 kg/m² (range: 36.6 – 76.3)	3%	Cost of GBP €8,240.		Dominates	Analysis of covariance showed that T2DM-related parameters account for most of the variability in incremental cost (approximately 25%). Only the variability of the base utility associated with the lowest BMI had a noteworthy impact on the variability of the incremental effectiveness of the intervention (8%). Results at different time horizons 5 years: dominates; 10 years €4,045/QALY gained; 15 years €90/QALY gained; 20 year dominates.

Key: AGB, adjustable gastric band; BPD, British Pound; DM, diabetes mellitus; DR, discount rate; EURO, Euro; GBP, gastric bypass; ICER, incremental cost-effectiveness ratio; LAGB, laparoscopic adjustable gastric band; LRYGBP, laparoscopic Roux-en-Y gastric bypass; LSG, laparoscopic sleeve gastrectomy; QALY, quality-adjusted life-years; RYGBP, Roux-en-Y gastric bypass; SG, sleeve gastrectomy; T2DM, type 2 diabetes mellitus; WTP, willingness to pay

Table 4: Generally accepted cost effectiveness (willingness to pay) thresholds for United States, United Kingdom, Sweden, Canada and Australia.

Country	Cost-effectiveness threshold	Comment
United States (USD)	$50,000 - $100,000/QALY gained	The United States has legislated against the explicit use of cost-QALY thresholds. Recent evidence suggests that if one had to select a single threshold outside the context of an explicit resource constraint or opportunity cost, use either $100,000 or $150,000.
United Kingdom (BPD)	£20,000/QALY gained and £20,000 – £30,000/QALY gained	The National Institute for Health and Care Excellence has never identified an incremental cost-effectiveness ratio above which interventions should not be recommended and below which they should. However, in general, interventions with an incremental cost-effectiveness ratio of less than £20,000 per QALY gained are considered to be cost effective. As the incremental cost-effectiveness ratio of an intervention increases in the £20,000 to £30,000 range, an advisory body's judgment about its acceptability as an effective use of National Health Service resources should make explicit reference to relevant factors outlined by the Institute.
Sweden (EURO)	€57,000/QALY gained	Relevant government authorities have suggested a threshold of SEK 500,000 (approximately €57,000).
Canada (CAD)	$20,000 – $100,000/QALY gained $124,000/QALY gained	Health-care programmes, which cost less than US$12,800 (CAN$20,000) per QALY are highly cost effective, but weak if the ratio exceeds US$64,000 (CAN$100,000).
Australia (AUD)	$50,000/QALY gained	Pharmaceutical Benefits Advisory Committee was unlikely to recommend a drug for listing if the incremental cost-effectiveness ratio (cost per life-year) exceeded AUD $76,000.

2.4 Discussion

This comprehensive systematic review synthesized disparate studies that investigated important health economic aspects of bariatric surgery as a treatment option for obesity. As an important advance on existing systematic reviews, our review included substantially more studies across the depth and breadth of the health economics literature than previous systematic reviews. We did not limit our review to full economic evaluations (cost-effectiveness and cost-utility studies). Despite the considerable heterogeneity of included studies and conflicting results from some individual studies for study populations such as T2DM, we found that common themes emerged. These themes included: bariatric surgery was generally considered cost-effective versus non-surgical interventions as a treatment option for people with morbid obesity; bariatric surgery was highly cost-effective and possibly cost-saving for severely obese patients with T2DM (mostly from observational and pre and post studies); only a limited spectrum of direct medical costs was considered in the majority of studies; disparate time horizons and cost information/data sources have been used; a wide range of methodological quality was an issue; a lack of consideration of the costs of many important longer term post-operative events like reoperations, complications and body contouring surgery; major gaps regarding the cost-effectiveness of bariatric surgery in particular target populations such as obese adolescents and men; and a paucity of information on indirect costs such as out-of-pocket expenses to patients and their families, work productivity gains and/or losses, and the impact of being waitlisted for 3 years on clinical and economic outcomes and the potential impact on patient prioritization decisions coupled with the concept of affordability of bariatric surgery, and the disproportionate increase in severe obesity where demand for bariatric surgery was continually exceeding the increase in supply.

2.4.1 Type 2 diabetes mellitus

A key finding of our systematic review was that bariatric surgery for the severely obese with T2DM was mostly cost-effective (mainly from observational and pre-post studies).

Another theme that emerged was that bariatric surgery as a treatment option for newly diagnosed T2DM was more cost-effective (or cost-saving) than for those with established comorbidity [65, 66, 68, 106]. A cost-effectiveness study based on small single-centred RCT data made the point that their results actually underestimated the cost-effectiveness of surgical therapy because they did not attempt to capture healthcare savings associated with the reduction of other obesity related morbidities or the improvements of quality of life associated with weight loss [65].

Contemporary debate about bariatric surgery as a treatment option for obesity is focused on the prioritization of particular patient groups where there are demonstrated clinical and economic benefits. A recent editorial argued that the indications for bariatric surgery should be viewed in terms of individual patient benefit without anticipating that there would be cost savings to a healthcare system by offering this treatment and that bariatric surgery clearly benefits some patients [27]. Patients considered for bariatric surgery should have a complication of obesity that is known to dramatically improve with weight loss surgery [27]. Examples include diabetes and osteoarthritis [27]. Nevertheless, we argue that policy and decision makers are increasingly asking not only whether an intervention works, but also whether it offers value for money [128]. More specifically, is the intervention cost-effective or even cost-saving. Bariatric surgery was identified as being highly cost-effective or even cost-saving for the severely obese with T2DM in the majority of studies. Bariatric surgery in early T2DM was found to be cost-saving, indicating that diversion of scarce healthcare resources should be considered for bariatric surgery for severely obese with T2DM.

Importantly, our review also highlighted the conflicting results of two recent studies that were informed by Swedish Obese Subjects study Swedish and Scandinavian clinical and cost data. The first study [24] modelled lifetime cost-utility analysis from the Swedish health payer perspective and revealed that bariatric surgery was cost-saving in all of the pre-specified diabetic cohorts (moderately, severely, morbidly and super-obese). In contrast, the second study (informed by long-term Swedish Obese Subjects data and cost data from Swedish sources) found no difference between the surgical and conventional treatment groups for patients with diabetes [106]. We also explored the cost-effectiveness results for all full economic evaluations of people with T2DM from 2009–2015. All of these studies found that bariatric surgery was cost-effective for severely obese people with T2DM. Additionally, sensitivity analyses found that the results were robust to changes in model parameters.

Accordingly, we argue that health economics studies that investigate bariatric surgery as a treatment option for people with T2DM should adopt full (rather than partial) economic evaluation underpinned by longer time horizons and be undertaken from a societal perspective. Furthermore, health economics effort should focus on bariatric surgery as a treatment option for people with T2DM with a BMI 30–34.9 kg/m^2 (non-severely obese).

2.4.2 Body contouring/bariplastic surgery

Our review has identified a major gap in the health economics reporting of bariatric surgery where body contouring/bariplastic surgery is a significant longer-term cost for many patients who experience massive weight loss after the intervention. This emerging and additional burden to the individual and/or society was not appropriately captured in the health economics reporting.

Patients requiring body contouring surgery after bariatric surgery have been described as a new and unique population that is difficult to manage, with 96% of post-bariatric surgery patients developing multiple redundant skin flaps [129]. An unfortunate consequence of massive weight loss is the persistence of large quantities of excess and often inelastic skin and subcutaneous tissue. These produce a hindrance to mobility, poor cosmesis, difficulties with wound healing, intertrigious dermatitis, compromised hygiene and potentially worsened overall patient body image despite weight loss [130]. Body contouring surgery that includes, but is not limited to, panniculectomy, (circumferential) abdominoplasty, breast reduction or lift, brachioplasty, and thigh lift serves to remove this excess tissue that remains after massive weight loss. Following body contouring surgery, significant improvements in self-image and quality of life, as well as hygiene, mobility and overall daily functioning have been reported [130].

Our review found that only 14% of included studies considered the costs of body contouring/bariplastic surgery in their analyses. Body contouring surgery as a follow-up procedure was first identified in this review's included studies over a decade ago. A 2002 study investigated the costs of in-patient care over 7 years among surgically and conventionally treated obese patients and concluded that a substantial fraction of the total hospital cost for surgical treatment of obesity emerged during the years after surgery [114]. Complications and sequelae of bariatric surgery cause some of these costs, but a substantial share is because of secondary plastic surgery [114]. A recent study from the UK, which reviewed funding models and access for bariplastic surgery, highlighted that there was very little in the literature on the prevalence of bariplastic surgery after bariatric surgery [121]. The only available and recent evidence based on a survey of 100 patients who had completed post-bariatric body contouring surgery in the Spanish public health system found that the cost of post-bariatric surgery body contouring treatment in a public health system unit was €8,264 (1.66 operations per patient) and that severe complications increase the average cost per patient 2.96 times [129].

Importantly, the study indicated that it provided conservative estimates (public health system costs) and the rate of complications was high (up to 50%), and that although the more severe complications are rare, these represent high costs (mean €24,463). Surveyed patients also undervalued the surgery's total costs (by 17.58% or €2,034). These costs are substantially higher than cost estimates currently included in cost-effectiveness and/or cost-utility studies that provided estimates based on abdominoplasty only (e.g. €2,604) [24].

Additionally, an enormous disparity exists between the number of people who desire a body contouring surgery and those who actually received it. Two recent studies noted that a majority of post-bariatric surgery patients desire body contouring surgery, particularly in certain body areas such as waist/abdomen, upper arms, and chest/breast. Financial resources and coverage from third-party payers may be an underlying cause for the discrepancy [122, 131]. From the literature, it was ascertained that bariatric surgery patients will opt to pay for body contouring surgery years after the initial procedure. Although many persons who have had a bariatric procedure will elect to have excess skin removed at a later date (at their own cost) after reaching a targeted weight, one study found that no such procedures occurred during the 2-year study period [55]. The most recent evidence suggests that body contouring surgery is the final stage of the massive weight loss patient's journey and that the obese patient's journey is not complete until redundant tissue is removed [132]. This study also found that around 70% of massive weight loss patients are left with redundant folds of tissue that impact on their quality of life and that these folds are heavy and cumbersome, and present functional and aesthetic problems. The surgical interventions to address these issues are much more complex than abdominoplasty and include procedures such as total body lift, upper or lower body lift, brachial lift, contouring of the trunk and medial thigh lift. [132].

Our review recommends that the longer term costs of massive weight loss (quality of life issues regarding redundant skin flaps and/or a desire for body contouring surgery) and the actual cost of body contouring surgery (generally at the patient's own cost) should be properly considered in full economic evaluations of bariatric surgery.

2.4.3 Waiting for surgery and relationship to patient prioritisation

Our review found that of 77 included studies, only one study investigated the impact of time delay on the clinical and economic outcomes of bariatric surgery. This is a key knowledge gap in the health economic reporting of bariatric surgery and is inextricably linked to the policy concept of patient prioritization for bariatric surgery. Recent scholarly literature found that public sector waiting times are years in duration in some countries and that there are physical (worsening of comorbidities and further weight gain) and psychosocial impacts for patients waiting for bariatric surgery [133, 134].

Constrained public sector budgets are one part of a tremendously complex system-wide healthcare landscape that results in severely and super-obese bariatric surgery candidates (with significant obesity-related comorbidities) experiencing multiyear wait times. A key reason for these multiyear wait times is the disproportionate rate of increase in severe obesity. To illustrate, a recent study identified that the National Health Service provision of bariatric surgery in the UK is ‘dwarfed by the rising tide of morbid obesity’ [135]. The study found that the number of National Health Service operations has ‘soared’ with a rise of over 300% from 2006-2007 to 2010-2011. Similarly, a recent Canadian study found that severe obesity has increased in prevalence by 400% (from 1 % to 4.3%) over two decades and is rising at a disproportionally faster rate than obesity. Additionally, the study indicated that to try and meet this increased demand, the number of publicly funded bariatric surgeries in Canada has increased 12-fold over two decades and that despite this trend, demand for surgery greatly exceeds supply [136]. The experience in the UK and Canada suggests that governments are increasingly funding bariatric surgery as a treatment option for people who meet clinical guidelines but that the increased demand for surgery is exceeding the increase in supply. It seems likely that funders' perceptions of 'affordability' are changing as bariatric surgery has increasingly become accepted as more than a cosmetic procedure and as the scale of the epidemic of severe obesity has become clearer.

As mentioned previously, a recent critique suggested that the indications for bariatric surgery should be viewed in terms of the individual patient benefit without anticipating that there will be cost savings to a healthcare system by offering this treatment. Nevertheless, further studies of affordability of bariatric surgery are warranted. Additionally, full economic evaluation of bariatric surgery as a treatment option could particularly investigate subgroups of patients that are languishing on public sector waiting lists for bariatric surgery such as patients with T2DM, CVD and/or severely or super obese.

2.4.4 Inclusion of complications and reoperations

Our review found that one-third of the included studies either ignored the costs and/or consequences of complications and reoperations, studies that accounted for reoperations and complications generally only accounted for short-term events, considered an incomplete list of complications or assumed relatively low probabilities of any of these the adverse events occurring. Additionally, many studies did not assume weight regain as an adverse event. Longer-term costs of bariatric surgery have therefore probably been underestimated, and the value for money for bariatric surgery subsequently overestimated.

A recent systematic review and meta-analysis concluded that overall complication rates associated with bariatric surgery range from 10% to 17% and reoperation rates approximately 7% [137]. Other studies claim that these complication rates are much higher (up to 33%) and that the rates of longer term complications are largely unknown because many patients present to non-specialist bariatric centres (rather than the short term complications that generally refer to the specialist surgeon) [138]. A study that explored the rates of complications and 'what a general surgeon needs to know' suggested that band erosion can occur early or years after surgery and in some series the reported incidence rate (when it is reported to a specialist centre) is up to 33% [138]. Another recent study on the costs of the major complications of leaks and bleeding following sleeve gastrectomy found that median additional costs for leaks were €9,284 (range €1,748–125,684) and €4,267 (range €1,524–40,022) for bleeding (2014 EURO) [139].

Clearly, complications and reoperations after the primary procedure are not uncommon, and the ongoing costs are potentially substantial. This is not appropriately reflected in many health economics analyses to date. Nevertheless, it is recognized that the issue of under reporting of complications and reoperations is a multidisciplinary problem. A recent Cochrane review concluded that assessing the risks of different bariatric procedures is still hampered by a lack of consistency and quality of evidence in the reporting of adverse outcomes and reoperation rates and that most studies followed participants for only 1 or 2 years; therefore, the long-term effects of surgery remain unclear [140].

The Cochrane review suggested that a core set of important adverse outcomes should be identified so that a standardized approach to reporting adverse outcomes can be developed [140]. Recently released standardized outcomes reporting clinical guidelines for metabolic and bariatric surgery partially addressed these issues from a clinical perspective [141]. We recommend that a consistent approach should also be adopted in all health economics reporting of bariatric surgery to ensure that relevant events are appropriately and consistently accounted for.

2.4.5 Health economics perspective, and reported costs and cost-effectiveness

A key finding of our review was that few studies were informed by the societal perspective. The actual resources included and unit costs employed in an analysis depend on its perspective [142]. In taking a societal perspective, one seeks to count all costs and benefits of medical interventions regardless of to whom they accrue [143]. In turn, the adoption of a narrow perspective in most health economics reporting of bariatric surgery with in-patients costs and/or a subset of outpatients costs such as clinic follow-up or laboratory testing only included directly translates to significant costs/cost offsets not being considered. Specifically, there is a paucity of identified out-of-pocket costs, costs to family members and other sectors (such as work force participation/productivity, absenteeism and presenteeism). Our review's included studies that employed a societal perspective were informed by a limited spectrum of these societal costs and/or benefits (such as productivity impacts or time-related costs); nevertheless, these studies found that the inclusion of these costs/cost offsets impacted on the results of the study.

Further, a recent health economics study argues that ignoring important costs and benefits in an economic evaluation will lead to an inefficient allocation of resources, in the short-term as well as the long-term perspective [144]. Another study makes the fundamental point that the economic burden of obesity is such that society incurs substantial indirect costs including years of disability, increased mortality before retirement, early retirement, disability pensions, and work absenteeism or reduced productivity. The study also suggests that the monetary value of lost productivity is several times larger than medical costs [145]. Thus, there is limited information available to policy makers and/or funders within public health systems to make fully informed decisions from a broader societal perspective as is appropriate given the wide-ranging impacts of obesity on society.

Another key finding of our review is that reported costs were very heterogeneous because the included studies' cost structures were largely informed by differing health economics perspective, time horizon and information sources. Similarly, there is a major knowledge gap in the assessment of costs of waiting for surgery. This narrow focus could be partly attributed to available data. Many studies relied on retrospective observational data from either large administrative databases such as healthcare plans or insurance data or single site administrative data such as hospital data. Measurement and valuation of identified costs also varies significantly across studies. To illustrate, some studies adopt broad average costs, other studies micro cost each input (for example each laboratory test and surgeons' time in the operating theatre). Costs are valued in different years and currencies and over different time horizons. Many studies inflate or deflate cost valuations to a base year, but some studies do not.

The way in which available resources are allocated against competing priorities is crucial in affecting how much health is generated overall and who receives healthcare interventions and who goes without. Cost-effectiveness analysis is a tool that can assist policy makers with resource allocation [146]. Nevertheless, caution needs to be exercised when comparing results of cost-effectiveness studies given variation in methodology such as perspective, time horizon, HRQoL instruments employed and the discount rates used [82]. We compared cost-effectiveness results with common outcomes and found that bariatric surgery was generally cost-effective and reported incremental cost effectiveness ratios less than the jurisdiction's willingness to pay thresholds irrespective of variations in methodology. Sensitivity analyses also showed that the bariatric surgery was cost-effective when varying changes in key assumptions such as BMI, age, time horizon and discount rate. Costs were also varied in sensitivity analyses; however, these studies largely only included direct medical costs, while costs of complications, reoperations and body contouring surgery were either substantially understated or ignored. One study's sensitivity analyses revealed that substantial changes in cost estimates had a major effect on the ICER value.

The choice of cost-effectiveness threshold is crucial in determining the value of healthcare interventions [110]. International willingness to pay thresholds vary as described in Table 4, and we acknowledge that there is ongoing debate in health economics about setting thresholds (e.g. using the World Health Organization-recommended cost-effectiveness thresholds of 1–3 GDP per capita versus cost-effectiveness thresholds reflecting opportunity costs). A recent study has suggested that rather than settling on a single threshold, it would be preferable to use multiple thresholds, ideally ones based on the available resources for the relevant decision maker and possible alternative uses of those resources. For example, decision makers in resource-poor settings would have a lower willingness to pay threshold [108].

Another key finding of our systematic review is that while many studies have addressed cost-effectiveness, no studies addressed the issue of affordability. As mentioned previously, it seems likely that funders' perceptions of ‘affordability’ have begun to change. We recommend that full economic evaluations of bariatric surgery not only consider a jurisdiction's willingness to pay, but also consider the results within the context of affordability under constrained government budgets.

A recent systematic review that investigated the costs of obesity described the disparate cost methodologies as comparing ‘apples and oranges’ and concludes that decision makers need to be aware of the different purposes and weaknesses of studies when interpreting cost outcomes [147]. Our review on the health economics reporting of bariatric surgery found considerable heterogeneity in reporting of costs for bariatric surgery. We therefore recommend thorough investigation and reporting of costs against a standardized framework such as the CHEERS checklist. We also recommend robust full economic analyses underpinned by a broad societal perspective and long-term time horizon.

2.4.6 Methodological quality

With the increasing number of publications available, transparency and clarity in reporting are important factors when reviewing the health economics literature [36]. Our review identified a wide range of methodological quality of included studies. We also identified that methodological quality has improved over time. To continue the trend in improved methodological quality, we recommend that the CHEERS statement is followed in future health economics assessments of bariatric surgery in order to further improve the quality of design, analysis and reporting.

2.4.7 Strengths and limitations

The key strength of our study was the comprehensive analysis of a disparate range of studies that report on health economics outcomes for bariatric surgery. We have systematically categorized, summarized, synthesized and analysed 77 studies. Our study aimed to provide a critical analysis of the key themes and evidence gaps in the existing scholarly literature. Heterogeneity of the literature was also a weakness; nevertheless, we did not seek to capture homogenous studies for meta-analysis to inform a further cost-effectiveness study. As an important alternative to inform the existing literature, we aimed to adopt a broader approach to our systematic review with a view to identifying common themes and key evidence gaps across the depth and breadth of the health economics literature.

2.5 Conclusions

Our comprehensive systematic review found that health economics reporting of bariatric surgery was characterised by heterogeneous approaches. Other key findings included a deficiency in reporting of important cost factors (because of the dominance of the healthcare system/third-party payer perspective, data sources and time horizons) and key complications and ongoing surgical costs (such as revisions, reversals and remedial body contouring surgery) in many studies. Bariatric surgery in particular subgroups of patients may be considerered to be cost-effective (and in some cases cost saving) such as severely obese and/or newly diagnosed T2DM.

Subgroups of patients that warrant further health economic investigation were identified, in particular adolescents, long-term waitlisted patients (particularly severely obese with T2DM) and severely obese men (generally a higher comorbidity load).

Therefore, we conclude that health economists investigating bariatric surgery should strive to undertake full economic evaluations that would rate at the highest levels for methodological quality against the CHEERS statement, underpinned by a societal perspective and broad life course costs and consequences. Only through such a robust approach will accurate measures of cost-effectiveness be established, and more reliable and targeted decision-making be implemented. Further, thorough investigation of costs and consequences will drive more accurate reporting of bariatric surgery complications and reoperations (including body contouring surgery).

Evidence from economic evaluation is used in healthcare decision-making if the evidence is accessible and acceptable [148]. Health economics reporting of bariatric surgery as a treatment option for obesity should serve to enhance clinical appraisal with robust and accessible health economic evidence. It is incumbent on the health economics community to educate decision and policy makers (who allocate scarce healthcare resources) about the different strengths and weaknesses of health economics reporting for bariatric surgery and to ensure that decisions are based upon the best quality and most relevant evidence available.

Contemporary debate about bariatric surgery as a treatment option for obesity is focused on the prioritization of particular patient groups for whom there are demonstrated clinical and economic benefits. There is also emerging debate on the impact of waiting times on patients' physical and psychosocial health, and their associated costs. The heterogeneity of the literature notwithstanding, on the basis of this review, there are clear signals to support the allocation of scarce resources to particular patients groups such as severely obese with T2DM. Health economists should also endeavour to investigate particular patient groups through robust full economic evaluation in order to provide more and better evidence in subgroups such as non-severely obese with T2DM, severely obese adolescents that are emerging as potentially cost-saving from a longer-term societal perspective and patients waiting long periods on public waiting lists for bariatric surgery.

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Appendix 2A: Publication of “Diverse approaches to the health economic evaluation of bariatric surgery: a comprehensive systematic review”.

obesity reviews doi: 10.1111/obr.12424

Chapter 3: A head-to-head comparison of the EQ-5D-5L and AQoL-8D multi-attribute utility instruments in patients who have previously undergone bariatric surgery.

Preface

Chapter 3 presents the first head-to-head comparison of two different multi-attribute utility instruments, namely the AQoL-8D and EQ-5D-5L, for a cross-sectional study of patients who received bariatric surgery in the private healthcare system many years previously (median (inter-quartile range) time since surgery 5 (3-8) years).

The systematic review in Chapter 2 found that the EQ-5D is the most commonly used multi-attribute utility instrument in cost-utility analyses of bariatric surgery, however, the classification system of the EQ-5D focuses on physical health, and has been shown to be relatively insensitive to changes in the psychosocial domains of health. Nevertheless, psychosocial health is an important consideration for people with severe obesity who have undergone bariatric surgery.

This study followed a systematic process in the selection of the two different multi-attribute utility instruments, supported by evidence-based rationale grounded in a comprehensive review and analysis of the multi-attribute utility instrument literature. The selection of the instruments was also discussed at formal meetings of the broader partnership project research team which comprised health economists, bariatric surgeons, allied-health clinicians, epidemiologists, government policy decision-makers and qualitative researchers.

There were key methodological justifications for selecting the two instruments. These justifications included that a small number of instruments dominate the economic evaluation literature with 63% of peer reviewed studies using the EQ-5D, and bariatric surgery cost-utility studies are dominated by the EQ-5D (3L and 5L). Nevertheless, the descriptive system of the EQ-5D-5L and AQoL-8D differ significantly, particularly with regard to the psychosocial domains of health where the AQoL-8D was developed with psychometric principles and subsequent testing. As a single multi-attribute utility instrument, the AQoL-8D captures the vast majority of domains of health considered crucial for people who are considering or who have undergone bariatric surgery.

The published paper presented in this chapter found that psychosocial health is one of the key drivers for people who have undergone bariatric surgery and that the AQoL-8D preferentially captured and assessed psychosocial health for people who had received bariatric surgery many years previously. This paper also explored the international dominance of the EQ-5D in the clinical and economic evaluation literature and suggested that the choice of multi-attribute utility instrument should be influenced by the innate sensitivities of the instrument to the relevant domains of health for the particular study

The findings from this study also guided the health-related quality of life studies contained in Chapters 4 and 5. These were longitudinal studies for long term publicly waitlisted patients who then received bariatric surgery.

This chapter has been published in *The Patient – Patient Centered Outcomes Research* (Appendix 3A).

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The published article found at the end of this chapter has been removed for copyright reasons.

Abstract

Background: Psychosocial health status is an important and dynamic outcome for bariatric/metabolic surgery patients, as acknowledged in recent international standardised outcomes reporting guidelines. Multi-attribute utility-instruments (MAUIs) capture and assess an individual's health-related quality-of-life (HRQoL) within a single valuation, their utility. Neither MAUIs nor utilities were discussed in the guidelines. Many MAUIs (e.g. EQ-5D) target physical health. Not so the AQoL-8D.

Objectives: Our objective was to explore agreement between, and suitability of, the EQ-5D-5L and AQoL-8D for assessing health state utility, and to determine whether either MAUI could be preferentially recommended for metabolic/bariatric surgery patients.

Methods: Utilities for post-surgical private-sector patients (n = 33) were assessed using both instruments and summary statistics expressed as mean [standard deviation (SD)] and median [interquartile range (IQR)]. Interchangeability of the MAUIs was assessed with Bland-Altman analysis. Discriminatory attributes were investigated through floor/ceiling effects and dimension-to-dimension comparisons. Spearman's rank measured associations between the

instruments' utility values and with the body mass index (BMI).

Results: Mean (SD) EQ-5D-5L utility value was 0.84 (0.15) and median 0.84 (IQR 0.75–1.00). Mean (SD) AQoL-8D utility value was 0.76 (0.17) and median 0.81 (IQR 0.63–0.88). Spearman's rank was r = 0.68; (p\0.001); however, Bland–Altman analysis revealed fundamental differences. Neither instrument gave rise to floor effects. A ceiling effect was observed with the EQ-5D-5L, with 36 % of participants obtaining a utility value of 1.00 (perfect health). These same participants obtained a mean utility of 0.87 on the AQoL-8D, primarily driven by the mental-super-dimension score (0.52).

Conclusions: The AQoL-8D preferentially captures psychosocial aspects of metabolic/bariatric surgery patients' HRQoL. We recommend the AQoL-8D as a preferred MAUI for these patients given their complex physical/psychosocial needs.

Key points for decision makers
Psychosocial health status has been increasingly identified as an important health-related quality of life outcome measure for the morbidly obese population who receive bariatric surgery.
Compared with the EQ-5D-5L, the AQoL-8D's descriptive/classification system (and subsequent utility valuation) preferentially captures psychosocial health status for people who have received bariatric surgery.
While the EQ-5D dominates the clinical and economic evaluation literature, choice of multi-attribute utility instrument should be influenced by the innate sensitivities of the instrument to the relevant domains of health for the study population.

3.1 Introduction

Obesity is a worldwide problem. Its extensive health repercussions include a high prevalence of psychological comorbidities, and it also has substantial negative economic impacts [1]. Many clinical and epidemiological studies find the most efficacious therapy for morbid obesity is metabolic/bariatric surgery [2, 3]. A systematic review of the impact of bariatric surgery on health-related quality-oflife (HRQoL) found physical HRQoL was improved to a significantly greater degree than mental HRQoL [4]. Furthermore, the psychosocial health status of bariatric surgery patients is dynamic [5]. This recent study found an initial improvement in mental health followed by deterioration between 4 and 9 years post-surgery. Potential reasons for this diminution of HRQoL were postulated to include disappointment from unrealistic expectations about surgical treatment, unforseen changes in eating behaviour, medical sequelae after surgery, dissatisfaction with body appearance and excess skin, and the reoccurrence of psychiatric disorders [5, 6].

The need to assess the psychosocial health status of bariatric surgery patients in the short, medium and longer terms has been increasingly identified [4–7], and underpins the quality-of-life component of recent guidelines on standardised outcomes reporting for bariatric surgery patients from the American Society for Metabolic and Bariatric Surgeons (ASMBS) [8, 9]. The guidelines made no specific recommendations regarding the most appropriate HRQoL instrument, the recommendation being only to use a ‘‘validated instrument(s)’’. Importantly, the measurement of psychosocial health or any domain of health is wholly dependent on the sensitivity of the instrument employed to assess that domain.

Health state utility values (HSUVs), or utilities, are important health economic metrics that assess the strength of preference for an individual’s health state relative to perfect health and death. Utilities are assessed relative to a 0.00–1.00 scale where 1.00 represents perfect health and 0.00 death [10]. The utility value therefore indicates the strength of preference for quality versus quantity of life [11], and quality-adjusted life-years (QALYs) can be calculated as the product of time spent in a health state and its utility. QALYs are a unit of benefit used in economic evaluation, namely cost-utility analysis (CUA) and, in principle, may be used to measure the HRQoL component of the burden of disease [10, 12]. Clinicians have also found that measuring health utilities is of benefit to patient– clinical assessment, relationships, communication and management [13]. Furthermore, utilities have been shown to be independent predictors of patient outcomes, including all-cause mortality and development of complications [14].

Multi-attribute utility instruments (MAUIs) are designed to rapidly and simply assess an individual's HSUV through application of pre-established formulae/weights to the array of responses to the MAUI's questions. Generic and disease-specific non-utility instruments may also be reduced to a single number; however, this number does not have independent meaning [10]. MAUIs thus differ fundamentally from generic HRQoL instruments.

Many MAUIs target physical health. For example, four of the five items in the EQ-5D, a well utilised international measure, relate to physical health. In contrast, 25 of the 35 items in the recently developed Assessment of Quality of Life (AQoL)-8D relate to psychosocial health [12]. Utility values assessed by MAUIs are not equivalent [15, 16], with the difference between the descriptive/classification systems of the MAUIs the principal determinant [15]. Differences in descriptive/classification systems are estimated to explain an average of 66 % of the difference between utilities obtained by MAUIs, and 81 % of the difference between the utilities of the EQ-5D-5L and AQoL-8D [15]. MAUIs are thus 'imprecisely related', a finding that threatens the comparability of economic evaluations that employ different instruments [17].

A small number of MAUIs dominate the economic evaluation literature [17]. A review of the Web of Science database (2005–2010) found that, of 1663 studies employing an MAUI, 63 % used the EQ-5D [15, 17]. Arguably, this finding reflects the recommendations of the UK National Institute for Health and Care Excellence (NICE) guidelines to use the EQ-5D as the preferred measure of HRQoL in adults [18]. These guidelines also acknowledge that the EQ-5D ‘‘may not be an appropriate measure of health-related utility in all circumstances’’ [19]. Emerging research is investigating the concept of ‘bolt-on’ dimensions to the EQ-5D in an attempt to broaden the classification system of this instrument [20, 21].

To inform debate on the choice of instrument for a particular patient group, it is important to compare different preference-based measures of health [22]. In particular, it is necessary to consider the applicability of the descriptive/ classification systems. Our study investigated a ‘head-to-head’ cross-sectional comparison of the EQ-5D-5L [23] and AQoL-8D [24] MAUIs for patients who have previously undergone bariatric surgery. The EQ-5D-5L and AQoL-8D have not been specifically validated for patients who have undergone bariatric surgery. This study explored agreement between, and suitability of, the AQoL-8D and EQ-5D-5L for assessing health state utility in patients who have received bariatric surgery to determine whether either instrument could be preferentially recommended in this study population.

3.2 Methods

3.2.1 Participants

Participants were individuals who had previously received bariatric surgery [predominantly laparoscopic adjustable gastric band (LAGB)] in the private sector (n = 33) in Tasmania, Australia. Clinical and socio demographic data were obtained during recruitment for a focus group designed to explore patient experiences following bariatric surgery. Participants were recruited with the aim of ensuring an appropriate mix of demographic/ clinical characteristics. Each participant was sent both MAUIs for self-completion at home 2 weeks before their focus group [13, 25]. All data were de-identified. Questionnaire responses were independently entered into a database by two authors and cross-checked before utilities were generated. Ethics approval was granted by the University of Tasmania's Health and Medical and Social Sciences Human Research Ethics Committees

3.2.2 Instruments

The EQ-5D-5L [23] is a recent augmentation of the EQ- 5D-3L [26], and the AQoL-8D [27] is the latest in the suite of AQoL instruments (AQoL-4D/6D/7D/8D) [28]. Table 1 provides a detailed comparison of the characteristics of both instruments. The EQ-5D-5L was developed to address the limited sensitivity (lack of descriptive richness and serious ceiling effects [29]) of the EQ-5D-3L. The EQ-5D-5L includes two additional levels for each of the five dimensions in the EQ-5D [30]. Nevertheless, it has the second lowest number of health states of the major MAUIs at 55 (3125). The EQ-5D-3L has the lowest, at 243. The EQ-5D-5L retains an optional visual analogue scale (EQ-VAS) in which patients rate their current health state on a scale of 0–100 (worst/best imaginable) [31].

The AQoL-8D is the fourth and most comprehensive of the AQoL suite of instruments, developed to achieve increased sensitivity in psychosocial dimensions of health, which was relatively neglected in other MAUIs, including earlier versions of the AQoL [10]. Both patient and public involvement were utilised during the construction of the AQoL-8D, a key element of robust MAUI development according to a recent systematic review by Stevens [33]. Psychometric principles were also employed during construction of the AQoL instruments, the only MAUIs to do so [32]. These key features of the AQoL-8D were not identified in the

Stevens [33] review. The AQoL-8D contains 35 questions and encompasses the largest number of health states of any existing MAUI (2.4 9 1023).

3.2.3 Data analysis

Baseline socio-demographic and clinical data are presented descriptively as mean [standard deviation (SD)] and/or median [interquartile range (IQR)] for continuous variables and frequency (%) for categorical variables. Body mass index (BMI) was calculated as weight (kg)/[height (m)]2.

HSUVs were generated for the EQ-5D-5L using the UK 'crosswalk' value set with the EQ-5D-5L version mapped (crosswalked) onto the 3L version through the preferred non-parametric model [34]. For the AQoL-8D, we used a scoring algorithm incorporating Australian weights published on the AQoL group's website (http://www.aqol.com. au). We assessed questionnaire completion by measuring the proportion of participants who completed the questionnaire and for whom an individual utility value could be generated.

Summary statistics of the HSUVs for each MAUI were assessed as mean (SD) and median (IQR) given the skewed nature of the data. Strength of correlation between the instruments' utility values for the sample was tested using Spearman's correlation coefficient, with Spearman's rho of greater than 0.50 or less than -0.50 considered strong, values between -0.49 to 0.30 and 0.30 to 0.49 considered moderate; and between -0.30 and 0.30 weak [35]. To determine interchangeability between the instruments, pairwise agreement between the utility values for each instrument for each participant was assessed using a scatterplot and through the Bland–Altman (BA) method of differences [36]. The difference between the two measures was plotted against the mean measurement for those two instruments for each individual, along with the limits of agreement (the range of values that would be expected to include 95 % of individual differences) [31].

An MAUI should be able to produce utility valuations for various health states with a significant degree of accuracy to effectively detect and represent differences between individuals [31]. Discriminatory attributes of the instruments were therefore assessed globally and then at dimensional levels. Globally, the extent of floor (worst health: -0.594 EQ-5D-5L and ?0.09 AQoL-8D) and ceiling effects (perfect health: 1.0 each instrument) was determined, and then utility values obtained on the alternate instrument were explored. At the dimensional level, summary statistics were obtained for the summary scores for each individual dimension of the AQoL-8D and its super-dimensions. The distribution of responses across the levels (1–5 or 6) of each of three psychosocial-related dimensions within each instrument was then explored. These dimension-to-dimension comparisons [22] encompassed anxiety/depression, self-care and pain/discomfort for the EQ-5D-5L, comprising one item each; and mental comprising eight, four and three items each, respectively.

The association between ‘current BMI’ and utility valuation obtained with each instrument was investigated by testing strength of correlation using the Spearman’s correlation coefficient.

Statistical analyses were undertaken using IBM SPSS (version 22) or R (version 3.0.2).

Table 1: Comparison of the dimensions and content of the EQ-5D-5L and AqoL-8D multi-attribute utility instruments.

Characteristics	EQ-5D-5L	AQoL-8D
Development team and year finalised	EuroQol Research Foundation, EuroQol Executive Office, Rotterdam, The Netherlands. (http://www.euroqol.org), 2011.	Centre for Health Economics, Monash University, Melbourne, Victoria, Australia. (http://www.aqol.com.au), 2011.
Number of health states described	3,125.	2.4×10^{23}.
Number of pages and questions	Two pages: EQ-5D-5L descriptive system 5 questions and EQ-5D Visual Analogue Scale.	Three pages: aqol1 to aqol35.
Mean completion time	< 1 minute.	5.45 minutes [27]
Valuation technique	Non-parametric indirect modelling technique and UK "crosswalk" set, [34]	Time Trade Off (Australian sample) [27]
Total number of dimensions	Five dimensions, one item in each. Each item has five levels of functioning scored as 1 (best) to 5 (worst). Participants choose one level for each item to describe their health status on the day of interview. Provides health state values as 11111 (best) to 55555 (worst).	Eight dimensions of between three to eight items, 35 items in total. Each item (aqol1 to aqol 35) has four to six levels scored as 1 (best) to 6 (worst). Participants choose one level for each item to describe health status over the past week.
Number of dimensions of physical health	Four dimensions – mobility, self-care, usual activities and pain/discomfort.	Three dimensions – (1) independent living 4 items (household tasks, getting around, mobility, self-care); (2) senses 3 items (vision, hearing, communication); and (3) pain 3 items (frequency of pain, degree of pain, pain interference). [10].
Number of dimensions of psychosocial health	One dimension – anxiety/depression with five levels of severity: (1) I am not anxious or depressed, (2) I am slightly anxious or depressed, (3) I am moderately anxious or depressed, (4) I am severely anxious or depressed, (5) I am extremely anxious or depressed.	Five dimensions – (4) happiness 4 items (contentment, enthusiasm, degree of feeling happiness, pleasure); (5) coping 3 items (energy, being in control, coping with problems); (6) Relationships 7 items (relationship with family and friends, social isolation, social exclusion, intimate relationship, family and community role); (7) self-worth 3 items (feeling like a burden, worthlessness, confidence); (8) mental health 8 items (feelings of depression, trouble sleeping, feelings of anger, self-harm, feeling despair, worry, sadness, tranquillity/agitation) [10].
Super-dimensions of physical and psycho-social health	No super-dimensions.	Two super-dimensions: physical super-dimension (PSD) and mental super-dimension (MSD). PSD includes independent living, senses and pain; MSD includes happiness, coping, relationships, self-worth and mental health [10]
Visual Analogue Scale	Yes.	No.
Range of reported utility scores from best possible health to worst possible health state	Range: states worse than dead <0 to full health 1.00, anchoring at dead=0. Scored range: -0.594 to 1.00 (UK crosswalk value set).	Range: full health 1.00 to anchoring at dead=0. Scored range: +0.09 to 1.00.
Available population norms	Ten countries in the crosswalk value set from EQ-5D-3L: Denmark, France, Germany, Japan, Netherlands, Spain, Thailand, United Kingdom, United States, Zimbabwe [34]. Australia [50].	Australia.

3.3 Results

3.3.1 Participants clinical and socio-demographic characteristics

Table 2 provides the participants' clinical and socio-demographic characteristics. Mean (SD) age was 56 (11) years, and two-thirds (n = 22; 67 %) were female. Mean (SD) of the maximum recorded BMI (before surgery) was 43.7 (7.3) kg/m2, and mean (SD) current BMI (at recruitment) was 32.8 (7.7) kg/m2. One-third of participants had obtained university qualifications and one-quarter were educated to year 10. Most participants (n = 32; 97 %) had received an LAGB, and 12 % (n = 4) of these participants had undergone a secondary procedure such as a revision. Median (IQR) number of years since primary surgery was 5.0 (3.0–8.0).

Table 2: Baseline sociodemographic characteristics of participants.

Characteristics	Private patients after surgery (n=33)
Age years Mean (SD)	56 (11)
Gender (n=x, %)	Male (n=11, 33%) Female (n=22, 67%)
BMI (kg/m^2) maximum (before surgery) Mean (SD)	43.7 (7.3)
BMI (kg/m^2) current (at recruitment) Mean (SD)	32.8 (7.7)
Years since primary procedure Mean (SD) Median (IQR)	 6 (6) 5 (3-8)
Highest level of education * Category (%)	category 1 (24.5) category 2 (15) category 3 (27.5) category 4 (33)
LAGB (n=x, %)	(n=32, 97%)
Laparascopic (n=x, %)	(n=33, 100%)
Secondary Procedure (n=x, %)	(n=4, 12%)

Data presented as mean (standard deviation (SD)) or n (%) unless otherwise indicated.
BMI, body mass index; IQR inter-quartile range; LAGB, laparoscopic adjustable gastric band.

3.3.2 Questionnaire practicality

All participants completed both MAUIs. The EQ-5D-5L was completed without omissions or additions (such as multiple responses to one question). In contrast, one participant attempted to select two response items to two questions and modify those items when completing the AQoL 8D. These nonconformities had no impact on our ability to assess the utility of this participant. As advised by the AQoL group, we used the worst response for utility generation.

3.3.3 Construct validity

Frequency distributions of the individual utility values for both instruments are provided in Figure 1a, b. Utilities obtained through both MAUIs showed a distribution towards perfect health, more so for the EQ-5D-5L than the AQoL-8D. There was no significant difference in mean and median utility values of both instruments, with a strong correlation overall. The range and IQR for the EQ-5D-5L (0.40–1.00 and 0.75–1.00) and the AQoL-8D (0.35–0.95 and 0.63–0.88) were the same (Table 3), but each was higher for the EQ-5D-5L, reflecting its greater negative skew. In turn, the AQoL-8D's assessed range and IQR for our study population compared with the potential scored range, measured as the difference between the floor to ceiling levels of +0.09 to 1.00, is proportionally larger than for the equivalent measure of the EQ-5D-5L. The inclusion of 1.00 in the EQ-5D-5L's range and IQR also reflect the ceiling effects of this instrument within our study population as detailed below.

The mean (SD) and median utility values tended to be higher [0.84 (0.15); 0.84] for the EQ-5D-5L than for the AQoL-8D [0.76 (0.17); 0.81], respectively (Table 3). A strong correlation was obtained between the utilities for the EQ-5D-5L and AQoL-8D (Spearman's rho 0.68; $p<0.001$). The EQ-VAS gave rise to mean (SD) and median (IQR) ratings of 76 (17) and 80 (70–90), respectively.

3.3.4 Sensitivity

A scatterplot of individual utility values (Fig. 1c) demonstrated two distinct groupings around 0.8 and 1.0 for the EQ-5D-5L. The BA plot (Fig. 1d) revealed a relatively wide limit of agreement (0.55) and systematic variation, notably a negative trend in the difference between individual participant utility values by mean value. No floor effects were identified for either instrument, nor were there ceiling effects for the AQoL-8D (Table 3). However, a ceiling effect was observed for over one-third (n = 12; 36 %) of participants with the EQ-5D-5L.

Table 4 provides the EQ-VAS rating scores and AQoL- 8D global utility values for each participant scoring perfect health using the EQ-5D-5L. One participant (number 11) rated themselves as experiencing perfect health on the EQVAS; however, their AQoL-8D utility valuation was high but not perfect (0.93). Overall, the mean (SD) and median (IQR) EQ-VAS ratings were 83 (10) and 84 (79–90), and the mean (SD) and median (IQR) AQoL-8D utility values were 0.87 (0.08) and 0.88 (0.84–0.93). Table 5 provides summary statistics for the individual and super-dimension scores of the AQoL-8D for the entire sample. The maximum score for the mental health dimension at 0.73 was markedly lower than for all other dimensions. The maximum score in the other seven individual dimensions was at least 0.96, six scoring 1.00. In turn, the maximum mental super-dimension score was 0.79. The mental health and mental super-dimensions also recorded the lowest mean (SD) and median (IQR) scores, at 0.62 (0.12) and 0.63 (0.52–0.73) and 0.44 (0.17) and 0.45 (0.27–0.54), respectively. Table 6 provides AQoL-8D individual and super- dimension scores for those recording perfect health using the EQ-5D-5L. One of these participants (Table 4, participant 11) achieved the maximum score (1.00) for the physical super-dimension (PSD). Given their AQoL-8D utility valuation was 0.93, this participant's overall health status was diminished due to psychosocial impacts. The maximum mental super-dimension (MSD) score within this group was 0.71. The mean

(SD) scores for the AQoL-8D PSD and MSD were 0.89 (0.07) and 0.52 (0.13), respectively. The findings are also reflected at the individual dimensions level of physical and psychosocial health. The physical health dimensions gave rise to the highest scores [independent living 0.97 (0.04), senses 0.92 (0.06), pain 0.95 (0.09)], and the psychosocial dimensions the lowest scores [happiness 0.85 (0.07), coping 0.87 (0.08), relationships 0.85 (0.12), self-worth 0.90 (0.08), mental health 0.65 (0.09)].

Table 7 provides a dimension-to-dimension comparison for each of three individual psychosocial-related dimensions of the EQ-5D-5L and AQoL-8D. The EQ-5D-5L showed a larger proportion of participants at Level 1 than theAQoL-8D for each dimension, and less dispersion overall. There were no participants rated at Level 4 or above within the psychosocial dimensions for the EQ-5D, unlike the AQoL-8D.

A moderate association was found between ‘current BMI’ and utility valuations for both the EQ-5D-5L and AQoL-8D with Spearman’s rho -0.37; p = 0.03 and -0.39; p = 0.02, respectively.

Table 3: Descriptive statistics of EQ-5D-5L abd AqoL-8D utility valuations, EQ-VAS scores and percent achieving worst or best health states.

MAUI (n = 33)	Mean (SD)	Median (IQR)	Minimum	% on floor	Maximum	% on ceiling
EQ-5D-5L	0.84 (0.15)	0.84 (0.75-1.00)	0.41	0	1.00	36 % (n = 12)
AQoL-8D	0.76 (0.17)	0.81 (0.63–0.88)	0.35	0	0.95	0
EQ-VAS	76 (17)	80 (70-90)	30	0	100	8 % (n = 1)

IQR, interquartile range MAUI, multi-attribute utility instrument; SD, standard deviation;.

Table 4: EQ-VAS rating and AqoL-8D utility valuation for each individual assessed in perfect health through the EQ-5D-5L.

Participant	EQ-5D-5L utility value	EQ-VAS rating	AQoL-8D utility value
1	1.00	85	0.82
2	1.00	80	0.95
3	1.00	90	0.90
4	1.00	80	0.84
5	1.00	65	0.85
6	1.00	90	0.95
7	1.00	83	0.94
8	1.00	90	0.84
9	1.00	75	0.80
10	1.00	90	0.92
11	1.00	100	0.93
12	1.00	70	0.66
Mean (SD)	1.0	83 (10)	0.87 (0.08)
Median (IQR)	1.0	84 (79-90)	0.88 (0.84-0.93)

IQR = interquartile range; SD, standard deviation; VAS, visual analogue scale.

Figure 1: Distribution of (a) EQ-5D-5L utility scores and (b) AqoL-8D utility scores. (c) Scatterplot of participants' utility scores for EQ-5D-5L and AqoL-8D. (d) Bland-Altman method of differences for utility scores between the EQ-5D-5L andAQoL-8D, all participants (n = 33)

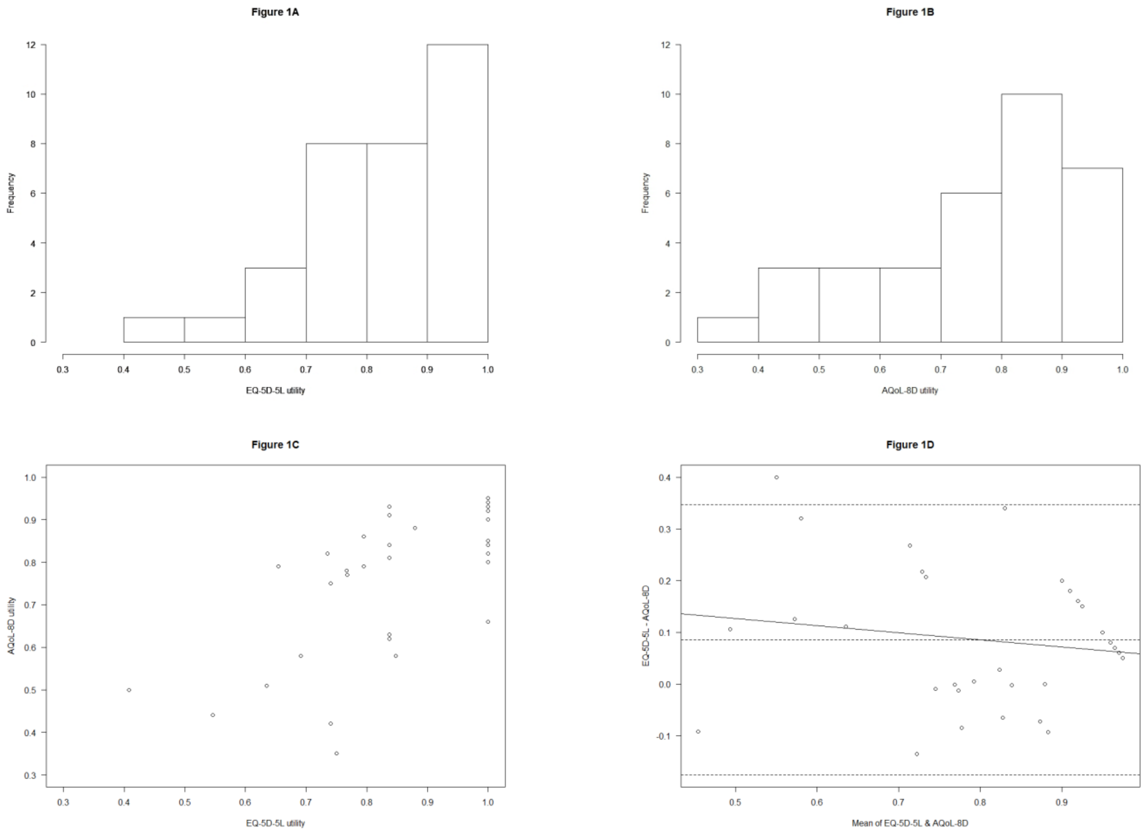

Table 5: AQoL-8D individual and super dimension scores for the entire sample (n = 33).

AQoL-8D dimension or super dimension (n = 33)	Mean (SD)	Median (IQR)	Minimum	Maximum
Dimensions of physical health (3)				
Independent Living	0.90 (0.14)	0.96 (0.85 – 1.00)	0.51	1.00
Senses	0.88 (0.10)	0.85 (0.82 – 0.95)	0.63	1.00
Pain	0.78 (0.20)	0.80 (0.63 – 0.95)	0.29	1.00
Dimensions of psychosocial health(5)				
Happiness	0.81 (0.11)	0.85 (0.75 – 0.89)	0.50	0.97
Coping	0.82 (0.13)	0.87 (0.77 – 0.90)	0.39	0.96
Relationships	0.77 (0.16)	0.82 (0.60 – 0.89)	0.49	1.00
Self-Worth	0.83 (0.14)	0.86 (0.75 – 0.92)	0.46	1.00
Mental Health	0.62 (0.12)	0.63 (0.52 – 0.73)	0.37	0.79
Super-dimensions (2)				
Physical super dimension (PSD)	0.73 (0.19)	0.75 (0.63 – 0.87)	0.34	1.00
Psychosocial super dimension (MSD)	0.44 (0.17)	0.45 (0.27 – 0.54)	0.10	0.73

IQR, inter quartile range; MSD, Psychosocial super dimension; PSD, Physical super dimension, SD, standard deviation.

Table 6: AQoL-8D individual dimension and super dimension scores for each individual assessed in perfect health through the EQ-5D-5L.

AQoL-8D dimension or super-dimension (n = 12)	Mean (SD)	Min	Max
Dimensions of physical health (3)			
Independent Living	0.97 (0.04)	0.90	1.00
Senses	0.92 (0.06)	0.84	1.00
Pain	0.95 (0.09)	0.72	1.00
Dimensions of psychosocial health (5)			
Happiness	0.85 (0.07)	0.73	0.97
Coping	0.87 (0.08)	0.71	0.96
Relationships	0.85 (0.12)	0.66	1.00
Self-Worth	0.90 (0.08)	0.70	1.00
Mental Health	0.65 (0.09)	0.43	0.78
Super dimensions (2)			
Physical super dimension (PSD)	0.89 (0.07)	0.80	1.00
Psychosocial super dimension(MSD)	0.52 (0.13)	0.27	0.71

SD, standard deviation.

Table 7: Distribution of levels of response for EQ-5D-5L individual dimensions of anxiety/depression, self-care, pain/discomfort with the AQoL-8D individual dimensions of mental health independent living and pain.

	EQ-5D-5L			AQoL-8D		
Dimension*	Anxiety/ Depression (1)	Self-care (2)	Pain/ Discomfort (3)	Mental Health (1)	Independent Living (2)	Pain (3)
Level						
1	64 %	97 %	49 %	24 %	63 %	43 %
2	24 %	3 %	30 %	39 %	24 %	39 %
3	12 %	0	18 %	30 %	8 %	15 %
4	0	0	3 %	5 %	5 %	3 %
5	0	0	0	2 %	0	0
6	NA	NA	NA	0	0	NA

* all columns add to 100%; NA, not applicable.

3.4 Discussion

To the best of our knowledge, our study is the first to investigate a 'head-to-head' comparison of the EQ-5D-5L and AQoL-8D MAUIs in patients who have undergone bariatric surgery. Our study's key finding was the divergent sensitivity of the instruments in assessing health state utility in this patient group, a difference arguably due to their ability to assess and capture psychosocial HRQoL impacts. This finding is crucial because psychosocial health status has been identified as a significant outcome for the morbidly obese population who receive bariatric surgery [4–6, 8, 9].

We found 36 % of participants were assessed as having perfect health on the EQ-5D-5L, but none on the AQoL- 8D. The mean utility valuation of the patient group scoring perfect health on the EQ-5D-5L was 0.87 using the AQoL-8D, the lower utility driven by less than perfect scores on the AQoL-8D MSD and, in all but one instance, the PSD. The assessed range for the EQ-5D-5L as a proportion of the potential scored range was less than for the AQoL-8D at 16 % [0.25/(1 - (-0.594))] and 27 % [0.25/(1 - 0.09)], respectively, indicating greater discriminatory attributes of the latter for this study population. These findings are partially explained by differences in the classification/descriptive systems and scoring algorithms of the two instruments. Additionally, the value sets are derived from two different populations, namely Australia and the United Kingdom, suggesting that these differences could also be partially explained by the different population sets.

EQ-5D-5L and AQoL-8D utility values were highly correlated by rank ordering (Spearman's rho 0.68); however, high correlation does not imply close agreement and is blind to the possibility of systematic bias [36]. We observed pairwise disagreement in utility values assessed for a given individual and evidence of systematic bias. In turn, the utility valuations obtained with these instruments in the population who underwent bariatric surgery are non-interchangeable. Our finding of non-interchangeability between the EQ-5D-5L and the AQoL-8D is consistent with a lack of pairwise agreement between the EQ-5D-3L and the AQoL-4D [25].

One of the key drivers for the development of the EQ- 5D-5L was to address serious ceiling effects of the EQ 5D-3L [23], with over 45 % of participants scoring perfect health in some studies [37, 38]. The severe ceiling effects of the EQ-5D-3L reflected difficulties in its ability to measure small and medium changes in health [23]. In an investigation of the EQ-5D-5L compared with the EQ-5D-3L across eight patient groups, the ceiling effect was reduced from 20 % (EQ-5D-3L) to 16 % (EQ-5D-5L), on average. Importantly, this study found that ceiling effects were higher for chronic diseases such as diabetes. In this population, the ceiling effect reduced from 34 % (EQ-5D-3L) to 28 % (EQ-5D-5L). In contrast, the ceiling effects for depression were reduced from 12 % (EQ-5D-3L) to 6 % (EQ-5D-5L) [30]. Arguably, this is a direct reflection of the specific question on depression/anxiety in the EQ-5D and underpins the importance of the descriptive systems employed.

Whilst floor/ceiling effects were not investigated in studies of bariatric surgery patients that employed the EQ- 5D-3L [39–41], over one-third of participants reported perfect health on the EQ-5D-5L in our study. This is a finding comparable to the extent of ceiling effects reported in recent studies that used the EQ-5D-5L for chronic conditions, including diabetes (n = 117 [42] and n = 289 [43]), end-stage renal disease (n = 150 [44]), and chronic hepatic disease (n = 1088 [45]), and consistent with the comparative findings above.

The ongoing ceiling effects measured in this and other studies indicate the limitations of the breadth of the EQ- 5D. Furthermore, research concerning the development of ‘bolt-on’ items for the EQ-5D has argued that these items could facilitate greater sensitivity for specific conditions, and further research has been encouraged [20]. However, it has also been noted that the use of 'bolt-on' items may lead to ''some variations in measurement between conditions and detract from the advantages of using a generic instrument'' [20]. We postulate that inclusion of one or more 'bolt-on' items may render results non-interchangeable, even with other 'EQ-5D' analyses and, in turn, the current dominance of this instrument irrelevant.

We found the mean, median and maximum scores of the AQoL-8D mental health and MSD were low relative to other AQoL-8D dimension scores for both the entire sample and the ceiling effect's subgroup for the EQ-5D. We also found greater dispersion for the AQoL-8D than the EQ-5D-5L across the three most comparable individual dimensions potentially impacting psychosocial health. We contend that together these findings support the greater sensitivity of the AQoL-8D than the EQ-5D towards psychosocial health.

In regard to the moderate correlations observed between utilities obtained from each instrument and 'current BMI', we contend that this finding is reflective of weight status being just one factor contributing to the HRQoL of people who have received bariatric surgery. This position is consistent with the most recent evidence, which does not support a direct link between long-term weight reduction and continued improvement/decline in mental health after bariatric surgery [5, 6]. Psychosocial support, alongside weight loss maintenance, are important management components for the HRQoL of this group of individuals in the longer term.

Economic evaluations of interventions that affect HRQoL commonly employ CUA that prioritise interventions according to the costs per QALY gained [15]. We found that significant differences in the EQ-5D-5L and AQoL-8D descriptive systems impact their sensitivity towards psychosocial domains of health. We also found that the utility values obtained cannot be used interchangeably. Impacts on psychosocial health for bariatric surgery patients have been identified as a vital outcome. Our findings thus have implications for the choice of utility instrument employed for clinical assessment and/or economic evaluation in the population for whom bariatric surgery is a consideration.

As noted previously, NICE's recommendation to use the EQ-5D for utility assessment is tempered by whether use of the EQ-5D is considered appropriate; a lack of content validity, including missing key health dimensions, is a primary concern [18]. If the nominated choice of instrument lacks sensitivity within a particular health context (or health domain), interventions affecting health states where the instrument's sensitivity is low will be disadvantaged [32], a potential bias of particular importance for healthcare decision makers. For people who are morbidly obese considering or having undergone bariatric surgery, the impact of any intervention will not be fully captured unless the nominated MAUI is sensitive to psychosocial health.

In turn, while the EQ-5D dominates the clinical/economic evaluation literature, its prevalence should not influence the choice of instrument in this (or other) study population(s). Rather, the choice of MAUI should be influenced by the sensitivity of the instrument to a patient group's health profile. In turn, we argue that the AQoL-8D should be further assessed for its responsivneness (compared to the EQ-5D-5L) in a prospective cohort study of morbidly obese subjects prior to receiving their bariatric surgery and at a more proximal timepoint following the bariatric surgery.

Within the ASMBS's recently published outcomes reporting guidelines for bariatric and metabolic surgery [8, 9], the EQ-5D was classified as one of several frequently used generic HRQoL instruments within this population; however, the ASMBS was unable to provide specific guidance as to a preferred HRQoL instrument(s), as previously noted. No reference was made to MAUIs per se; a situation we believe is an important oversight. If a MAUI and associated utility valuation comprehensively assesses and captures the physical and psychosocial domains of health for bariatric surgery patients, use of such an instrument could fulfil ASMBS HRQoL requirements. Related economic evaluations would also be underpinned by robust utility valuation, and thus facilitate defensible resource allocation.

Respondent burden is also a necessary consideration in instrument choice. The ASMBS document argues that HRQoL instruments with more items are less likely to be completed by patients, whereas instruments with fewer items are completed at higher rates. We expected the EQ-5D-5L would achieve a higher level of completion given that it comprises 30 fewer items than the AQoL-8D. Additionally, the average time for completion for the EQ-5D-5L (1 min), is approximately 4 min faster than that for the AQoL-8D (Table 1). Our study showed a 100% response rate for both instruments and subsequent generation of individual utility values. Nevertheless, we acknowledge that our study participants were fully engaged through focus group involvement and that this may have influenced the completion rate of the MAUIs for our study. As participant levels of education were relatively evenly spread, this should not confound questionnaire completion.

The ASMBS document also recommends, with reference to a 2011 review of HRQoL instruments measuring bariatric surgery [46], the use of a combination of HRQoL instruments to capture psychosocial impacts. The 2011 review found that while several generic and obesity specific instruments have been developed and/or used in bariatric surgery, all have limitations [46]. The review investigated the content validity of one MAUI (EQ-5D) and other generic and disease-specific instruments, including the SF-36, Nottingham Health Profile and IWQoL-lite. The review consequently proposed a conceptual framework for a bariatric surgery-specific HRQoL instrument that comprised

20 items, 19 of which, including all of the psychosocial domains of health, are included in the AQoL-8D. The item not included in the AQoL-8D pertained to eating. This conceptual framework subsequently underpinned the development of the disease specific quality-of-life instrument, the 'bariatric and obesity-specific survey' (BOSS) [47]. The BOSS is not an MAUI. The BOSS-42 (the final version of this instrument) contains 42 items, seven more than the AQoL-8D.

Thus, our study found that a single MAUI instrument, the AQoL-8D, is sensitive to the psychosocial as well as the physical domains of health for people who have undergone bariatric surgery, and it captures the vast majority of domains considered crucial in this population. While the length of the AQoL-8D may be an initial deterrent, this concern must be balanced against the sensitivity of this instrument to mental health [48] and physical health dimensions. Further, the use of a combination of up to three or four HRQoL instruments could be more burdensome and time consuming for the study population than the use of a single comprehensive instrument.

The major strength of this study is the use of a homogeneous group of bariatric surgery patients to minimise confounding due to patient characteristics in the identification of similarities and key differences between the EQ-5D-5L and AQoL-8D. The key limitation of this study is the sample size (n = 33). Nevertheless, we found that about one-third of the participants scored perfect health on the EQ-5D-5L, which is consistent with other studies of chronic disease with larger samples. Another limitation is that we did not include a disease-specific instrument because of concerns about the potential impact of respondent burden on both the quantitative and the qualitative components of the broader study. In lieu of a disease specific instrument, we compared the utility valuations of 'current BMI'. One further limitation could be attributed to the utilities estimated from the EQ-5D-5L crosswalk value set [49]. Another limitation is that the value sets for the two MAUIs are derived from two different populations (Australia for the AQoL-8D and United Kingdom for the EQ-5D-5L). Finally, given this study was exploratory, larger confirmatory studies are justified. We also suggest that a comparison between the AQoL-8D and SF-6D would be of value.

3.5 Conclusions

Before selecting a generic MAUI, researchers should fully understand the instruments' descriptive/classification systems and the innate sensitivities of the MAUI in their context. Given the relative importance of the psychosocial health in the population contemplating or having undergone bariatric surgery, the choice of MAUI may be crucial. For bariatric surgery, the AQoL-8D more fully captured and assessed the psychosocial aspects of these patients' HRQoL as compared with the EQ-5D-5L. Additionally, the AQoL-8D was sensitive to the physical aspects of these patients' HRQoL. We recommend the AQoL-8D as a preferred MAUI to the EQ-5D-5L for patients undergoing bariatric surgery given their complex physical and psychosocial needs.

3.6 References

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Appendix 3A: Publication of "A head-to-head comparison of the EQ-5D-5L and AQoL-8D multi-attribute utility instruments in patients who have previoulsy undergone bariatric surgery".

Chapter 4: An exploratory study of long-term publicly waitlisted bariatric surgery patients' quality of life before and 1 year after bariatric surgery, and considerations for healthcare planners.

Preface

This chapter is one of two longitudinal studies (Chapters 4 and 5) that were based on a unique cohort of long-term waitlisted patients (mean (standard deviation) years on the waiting list 6.5 (2) years) who were then provided with bariatric surgery due to a public policy decision to reduce waiting lists. This longitudinal study's cohort of patients purposely contrasts with Chapter 3's cross-sectional study and cohort of patients who had received bariatric surgery many years previously (median (interquartile range) 5 (3 – 8) years) in the private healthcare system.

Chapter 2's comprehensive systematic review established that only one study (of the 77 included studies) investigated the impact of time delay on the clinical and economic outcomes of bariatric surgery. This key knowledge gap is also linked to the policy issue of patient prioritisation for bariatric surgery. The systematic review also suggested that constrained public sector budgets are one part of a tremendously complex system-wide healthcare landscape that results in people with severe and super-obesity (generally with significant obesity-related comorbidities) experiencing multiyear wait times.

Chapter 4's selection of the EQ-5D-5L and AQoL-8D multi-attribute utility instruments was also guided by the systematic review (Chapter 2) and the findings of Chapter 3 that established the AQoL-8D (compared to the EQ-5D-5L) was sensitive to the complex psychosocial health for people who had undergone bariatric surgery many years previously.

Chapter 4's published study is the first study to measure health state utility values (both instruments) and individual and super dimension scores (AQoL-8D) for the increasingly prevalent study population of long-waiting public sector bariatric surgery patients who carry complex physical and psychosocial health related quality of life needs, before and 1 year after surgery.

This study investigates health-related quality of life before, 3 months and one year after bariatric surgery using both the EQ-5D-5L and AQoL-8D for severely obese long-waiting public healthcare bariatric surgery patients. The derivation of utilities for this important subgroup of bariatric surgery patients is extremely useful for informing current policy decisions and as an input to future economic evaluations.

The study's finding of statistically improved health-related quality of life for long-waiting public healthcare sector patients following bariatric surgery is important, as is information about how the AQoL-8D and EQ-5D-5L instruments perform in this study population. It was identified that the AQoL-8D preferentially captured and assessed psychosocial health when compared with the EQ-5D-5L. Additionally, the finding that the psychosocial dimensions of health drove the health-related quality of life improvements is also crucial in understanding the value of surgical benefits obtained for patients. Another key finding of this study was the maintenance of the quality of life gain out to 1 year post operatively.

This study provided much needed policy advice to the NHMRC project partner regarding the health gains that can still be realised when long-waiting bariatric surgery patients are ultimately treated. The study suggested that long-waiting bariatric patients should not be 'written-off' by healthcare planners: they can still realise significant improvements in health-related quality of life outcomes when ultimately treated, and this should be factored into patient prioritisation decisions.

This chapter has been published in *PharmacoEconomics – Open* (Appendix 4A). A fee waiver was granted for this publication.

Impact factor: *PharmacoEconomics – Open* is a new journal, nevertheless, the impact factor of *PharmacoEconomics* (the companion journal) is 3.63.

Campbell JA, Hensher M, Neil A, Venn A, Wilkinson S, and Palmer AJ. An Exploratory Study of Long-Term Publicly Waitlisted Bariatric Surgery Patients' Quality of Life Before and 1 Year After Bariatric Surgery, and Considerations for Healthcare Planners. *PharmacoEconomics-Open*. 2017:1-4. DOI:10.1007/s41669-017-0038-z

Abstract

Background: Long-term publicly waitlisted bariatric surgery patients typically experience debilitating physical/psychosocial obesity-related comorbidities that profoundly affect their quality of life.

Objectives: We sought to measure quality-of-life impacts in a study population of severely obese patients who had multiyear waitlist times and then underwent bariatric surgery

Methods: Participants were recruited opportunistically following a government-funded initiative to provide bariatric surgery to morbidly obese long-term waitlisted patients. Participants self-completed the EQ-5D-5L and AQoL-8D questionnaires pre- and postoperatively. Utility valuations (utilities) and individual/super dimension scores (AQoL-8D only) were generated.

Results: Participants' (n = 23) waitlisted time was mean [standard deviation (SD)] 6.5 (2) years, body mass index reduced from 49.3 (9.35) kg/m^2 preoperatively to 40.8 (7.01) 1 year postoperatively (p = 0.02). One year utilities revealed clinical improvements (both instruments). AQoL-8D improved significantly from baseline to 1 year, with the change twice that of the EQ-5D-5L [EQ-5D-5L: mean (SD) 0.70 (0.25) to 0.78 (0.25); AQoL-8D: 0.51 (0.24) to 0.67 (0.23), p = 0.04], despite the AQoL-8D's narrower algorithmic range. EQ-5D-5L utility plateaued from 3 months to 1 year. AQoL-8D 1-year utility improvements were driven by Happiness/Coping/Self-worth (p<0.05), and the Psychosocial super dimension score almost doubled at 1 year (p<0.05). AQoL-8D revealed a wider dispersion of individual utilities.

Conclusions: Ongoing improvements in psychosocial parameters from 3 months to 1 year post-surgery accounted for improvements in overall utilities measured by the AQoL-8D that were not detected by EQ-5D-5L. Selection of a sensitive instrument is important to adequately assess changes in quality of life and to accurately reflect changes in quality-adjusted life-years for cost-utility analyses and resource allocation in a public healthcare resource-constrained environment.

Key points for decision makers
Psychosocial health status is an important health-related quality of life (HRQoL) outcome for long-waiting bariatric surgery patients. Whilst the EQ-5D is prevalent in the economic evaluation of bariatric surgery, compared with the EQ-5D-5L, the AQoL-8D preferentially captures and assesses psychosocial health for this study population
If used in the clinical setting, utility valuations and individual and super dimension scores could provide both clinicians and healthcare decision-makers with important information regarding HRQoL impacts for people who have waited many years in the public health system for their bariatric surgery
Long-waiting bariatric patients should not be 'written-off' by healthcare planners; they can still realise significant improvements in HRQoL outcomes when ultimately treated, and this should be factored into patient prioritisation decisions.

4.1 Introduction

Obesity is a profoundly complex global public health, economic, and strategic policy problem [1–5]. Bariatric (obesity or metabolic) surgery is generally considered the most efficacious and cost-effective treatment intervention for people with intractable severe or morbid obesity, particularly for subgroups of patients such as people with type 2 diabetes [6–13]. A recent comprehensive systematic review of 77 diverse health economics studies that reported on bariatric surgery from 1995 to 2015 found the EQ-5D is the prevalent multi-attribute utility instrument (MAUI) used in cost-utility analyses of bariatric surgery worldwide, and the impact of time delay for publicly waitlisted patients on the clinical, quality-of-life, and economic outcomes of bariatric surgery has been largely ignored [14].

As an important subgroup of bariatric surgery patients, long-term morbidly obese, publicly waitlisted, bariatric surgery patients generally experience increased physical and psychosocial comorbidity loads that ultimately translate to 'sicker' patients demanding proportionally more of the scarce healthcare dollar [14–17]. Recent qualitative evidence has indicated that waiting for bariatric surgery can lead to development of new or worsening obesity-related comorbidity or decline in mobility and be emotionally challenging ('frustrating', 'depressing', 'stressful') [18]. Additionally, the need to assess the psychosocial health status of bariatric patients in the short, medium, and longer terms has been increasingly identified [19] and recognised as crucial for bariatric surgery patients [20–24]. Moreover, the psychosocial health status of bariatric surgery patients is dynamic, some studies suggesting an improvement up to 4 years and declining thereafter [22, 24]. Other studies suggest that quality of life significantly improves up to 1 year and is maintained at 2 years [25]. Importantly, there is a paucity of quantitative evidence concerning the health-related quality of life (HRQoL) impacts for the group of long-waiting, public healthcare patients who then undergo bariatric surgery.

Within resource-constrained healthcare budgets, funders' perceptions of 'affordability' are changing as bariatric surgery has increasingly become accepted as more than a cosmetic procedure for obesity and as the scale of the epidemic of severe obesity has become clearer [14]. Furthermore, the allocation of public-sector budgets is one part of a tremendously complex healthcare landscape that results in severely obese bariatric surgery candidates (with complex obesity-related comorbidities that translate to diminished HRQoL) experiencing multiyear wait times [14, 15]. A key reason for these multiyear wait times is the disproportionate rate of increase in severe obesity, and therefore the ever increasing demand for bariatric surgery surpassing the relatively static supply [17, 26].

Recent evidence has highlighted the differences and disagreements regarding the prioritisation of quality-of-life outcomes by health professionals and patients [27], revealing that patients prioritised seven quality of life items, none of which were prioritised by professionals. Surgeons prioritised only one quality-of-life outcome (versus four to 11 in the other health professionals' subgroups, e.g. nurses and dieticians) [27]. These findings highlight the importance of individual, self-reported patient assessments of HRQoL in the bariatric surgery population.

Standardised outcomes reporting guidelines for metabolic and bariatric surgery were developed by the American Society of Metabolic and Bariatric Surgeons (ASMBS) to drive consistency of reporting clinical and HRQoL outcomes within the field [20, 21]. These guidelines acknowledge that whilst bariatric surgery produces marked weight loss and improvement of physical comorbidities, the impact on HRQoL is less well established [20, 21]. The guidelines did not provide specific recommendations regarding the reporting of health state utility values, also described as utility valuations or utilities [24].

Utility valuations are important health economic metrics that assess the strength of preference for an individual's health state relative to perfect health and death, and importantly have inherent independent meaning [24, 28]. Utilities are assessed relative to a 0.00–1.00 scale, where 1.00 represents perfect health and 0.00 represents death, and therefore indicates the strength of preference for quality versus quantity of life [29]. Utilities are also a vital component of cost-utility analysis (a commonly used form of full economic evaluation that assesses the incremental costs of an intervention versus the incremental gains in quality-adjusted life-years) [12, 29, 30].

MAUIs are designed to rapidly and simply assess an individual or study population's utility valuation(s) through the application of pre-established formulae/weights to the array of patient-reported responses to the instrument's questions (generally self-reported through, for example, clinic visits, mail-outs, or the Internet) [24, 31, 32]. Based on patient-reported responses to MAUIs' questionnaires, the algorithm of a given instrument generates utility valuations. Many instruments generate utilities that are less than zero described as a health state perceived to be worse than death (e.g. the most recent EQ-5D-5L UK value set range: -0.281 to 1.0 [33, 34]). Most instruments report minimal clinically important differences or minimal important differences for their utilities [35–37].

The EQ-5D-5L is an internationally prevalent MAUI used in the assessment of patient-reported quality-of-life outcomes and full economic evaluations of treatment interventions (including bariatric surgery) [14, 38]. Recent evidence has suggested that for the EQ-5D-3L (precursor to the 5L), a 1.0-unit decrease in body mass index (BMI) is associated with a 0.0051- to 0.0075-

utility point increase. For a 1.0-unit decrease in BMI, the study reported a 0.0051 increase in utility when adjusted for baseline presence of comorbidity (stepwise approach); a 0.0052 increase in utility when adjusted for age, sex, and baseline BMI; a 0.0068 increase in utility when adjusted for age, sex, baseline BMI, and baseline comorbidity; and a 0.0075 increase in utility associated with the primary (baseline) analysis [39].

The AQoL-8D MAUI is informed by psychometric principles and testing and has been found to preferentially capture psychosocial health for people who had already undergone bariatric surgery many years previously in the private healthcare system {median [interquartile range (IQR)] 5 (3–8) years} [24, 40, 41]. This study also found that the AQoL-8D and EQ-5D-5L instruments were not interchangeable for the study population and that body weight is just one factor contributing to the complex HRQoL [24]. A recent study that investigated cross-sectional quality-of-life data using the Moorehead–Ardelt Quality of Life Questionnaire II also found that quality of life after bariatric surgery is not just dependent on weight loss [42]. Nevertheless, the Moorehead–Ardelt Quality of Life Questionnaire II is not an MAUI.

Another recent study suggested that clear preoperative predictive markers of well-defined postoperative success following bariatric surgery would be invaluable and facilitate a more refined and evidence-based mechanism by which to select patients for bariatric surgery [43]. The study found that it is important to explore the relationships between preoperative clinical parameters and HRQoL in those morbidly obese patients who are eligible for bariatric surgery, and that identifying those clinical and psychosocial predictors of success assumes great significance when selecting (or prioritising) patients for bariatric surgery [43]. A recent systematic review that investigated quality-of-life outcomes for bariatric surgery patients found that the SF-36 was the most commonly used HRQoL instrument in the review's 13 included studies (control group was one of the inclusion criteria) [25]. Utility valuations were not generated in these studies [25]. Importantly, utility valuations have been shown to be independent predictors of patient outcomes in patients with type 2 diabetes, including all-cause mortality and development of complications [44]. Clinicians have also found that measuring utilities is of benefit to patient– clinical assessment, relationships, communication, and management [32].

Our study arose from a targeted State Government of Tasmania, Australia, policy decision to reduce Tasmanian public hospital surgical waiting lists. This initiative provided us with a novel and exploratory opportunity to recruit a cohort of morbidly obese, long-term waitlisted, bariatric surgery patients who then underwent bariatric surgery as a result of this policy initiative. This provided us with the opportunity to investigate an important and increasingly prevalent study population of bariatric surgery patients who inherently carry complex physical and psychosocial HRQoL needs. We aimed to investigate the physical and psychosocial HRQoL changes in these patients by using the EQ-5D-5L and AQoL-8D MAUIs to generate utility valuations (both instruments), and the AQoL-8D's individual dimensional scores (namely, Independent Living, Senses, Pain, Happiness, Coping, Relationships, Self-worth, and Mental Health) and super dimensional scores (namely, the composite Physical super dimension of Independent Living, Senses, and Pain; and the composite Psychosocial super dimension of Happiness, Coping, Relationships, Self-worth, and Mental Health) preoperatively and at two postoperative time points (namely, 3 months and 1 year). We also aimed to explore the HRQoL benefits of bariatric surgery for long-term waitlisted patients and concomitance with BMI changes. We further aimed to investigate whether the MAUIs would reveal significant psychosocial HRQoL impacts at 1 year postoperatively. We also aimed to explore whether utility valuations and individual and super dimension scores could provide healthcare decision-makers with important information regarding HRQoL impacts for people who had waited many years in the public health system for their bariatric surgery.

4.2 Methods

4.2.1 Study design

(i) Recruitment of participants

A Tasmanian government policy decision was made in 2014 to allocate additional and targeted public funds to provide morbidly obese, long-term waitlisted patients with bariatric surgery in 2015. The policy decision provided us with an opportunity to recruit bariatric surgery patients who had waited for their surgery in a public healthcare system for many years. Appropriate ethics approvals were obtained from our University's Health and Medical Human Research Ethics Committee before commencement of our study's recruitment of participants.

We subsequently invited patients who were identified for bariatric surgery to participate in our study. Participants were provided an information package and consent materials before their bariatric surgery pre-admission clinic. The process for participants' questionnaire completion after consenting to participate in the study is outlined in Sect. 4.2.1.(ii).

Participants who consented to participate in our quality-of-life study underwent publicly funded laparoscopic adjustable gastric banding (LAGB) surgery by the same surgeon in the Hobart Private Hospital. Laparoscopic banding was carried out using Apollo APS or APL bands, with adjustment ports attached to the left anterior rectus sheath [45]. Postoperative fluid diets were maintained for 3 weeks, with subsequent transition to normal foods, accompanied by instruction on eating technique and exercise

(ii) The multi-attribute utility instruments and questionnaire completion

Our earlier study comparing the EQ-5D-5L and AQoL-8D MAUIs for people who had undergone LAGB surgery many years previously provided a detailed summary of the divergent characteristics of the two purposively selected MAUIs [24]. Table 1 provides an overview of these characteristics. In summary, the EQ-5D-5L is an internationally prevalent instrument (e.g. from 2005 to 2010, the EQ-5D was used in 63% of economic evaluations) [38]; the EQ-5D instrument is prevalent in the full economic evaluation of bariatric surgery [14]; it describes 3125 health states (compared with 243 health states of the EQ-5D-3L precursor to the 5L); four of the five instrument's health domains/classifications focus on physical HRQoL; and it takes less than 1 min to complete the EQ-5D-5L's questionnaire. The EQ-5D-5L also contains a visual analogue scale (EQ-VAS). In contrast, the AQoL-8D's classification system is supported by psychometric principles and testing, and 25 of the instrument's 35 items capture and assess five (from eight) psychosocial domains of health (Happiness, Coping, Self-worth, Relationships, and Mental Health). The AQoL-8D describes billions of health states and takes 5 min to complete [40, 41].

Participants were asked to self-complete both instruments' questionnaires before their bariatric surgery at the pre-admission preoperative clinics (generally one to two weeks before their surgery) and at two postoperative reportable time points, namely 3 months and 1 year after their bariatric surgery. Postoperative questionnaires were mailed out for self-completion with an explanatory cover letter and reply paid envelope enclosed. The order of instrument completion was not included in the explanatory letter, nor monitored at the pre-admission clinics. We evaluated the EQ-5D-5L and AQoL-8D questionnaire completion by assessing the overall proportion of participants who completed the questionnaire(s) at the study's three time points for whom an individual utility value could be generated (outlined in Sect. 2.2).

Table 1: Comparison of the dimensions and content of the EQ-5D-5L and AqoL-8D multi-attribute utility instruments.

Characteristics	EQ-5D-5L	AQoL-8D
Number of health states described	3,125.	$2.4 * 10^{23}$.
Total number of dimensions	Five dimensions, 1 item in each. Each item has 5 levels of severity scored as 1 (best) to 5 (worst).	Eight dimensions of between 3 to 8 items, 35 items in total. 25 of the 35 items capture and assess psychosocial domains of health.
Number of dimensions of physical health	Four dimensions: mobility, self-care, usual activities and pain/discomfort.	Three dimensions: (1) Independent Living, 4 items (household tasks, getting around, mobility, self-care); (2) Senses, 3 items (vision, hearing, communication); and (3) Pain, 3 items (frequency of pain, degree of pain, pain interference).
Number of dimensions of psychosocial health	One dimension: anxiety/depression with five levels of severity: (1) I am not anxious or depressed, (2) I am slightly anxious or depressed, (3) I am moderately anxious or depressed, (4) I am severely anxious or depressed, (5) I am extremely anxious or depressed.	Five dimensions – (4) Happiness, 4 items (contentment, enthusiasm, degree of feeling happiness, pleasure); (5) Coping, 3 items (energy, being in control, coping with problems); (6) Relationships, 7 items (relationship with family and friends, social isolation, social exclusion, intimate relationship, family role and community role); (7) Self-worth, 3 items (feeling like a burden, worthlessness, confidence); (8) Mental health, 8 items (feelings of depression, trouble sleeping, feelings of anger, self-harm, feeling despair, worry, sadness, tranquillity/agitation).
Super dimensions of physical and psychosocial health	No super dimensions.	Two super dimensions: Physical super dimension (PSD) and Psychosocial super dimension (MSD). PSD includes independent living, senses and pain; MSD includes happiness, coping, relationships, self-worth and mental health.

4.2.2 Data analysis

Participants with patient-reported HRQoL assessments for one or both instruments, for at least one time point where the MAUI algorithm (either instrument) could generate the instrument's utility valuations or scores were included in the analyses (Table 2).

Baseline socio-demographic and clinical data were analysed descriptively as mean [standard deviation (SD)] for continuous variables and frequency (%) for categorical variables. BMI was calculated as weight (kg)/[height (m)]^2. Percentage total weight loss was calculated as weight loss (kg)/initial weight (kg) x 100, and percentage excess weight loss was calculated as total weight loss/{initial weight - [25 x height $(m)^2$]} x100. Height and weight data were collected from medical records at the study's three time points.

Utility valuations were generated for the EQ-5D-5L using the most recent UK value based on directly elicited preferences [33, 34] (range: -0.281 to 1.00 utility points) and for the AQoL-8D using the most recent Australian scoring algorithm available on the AQoL group's website (http://www.aqol.com.au) (range: +0.09 to 1.0 utility points). Summary statistics of both MAUIs' utility valuations and EQ-VAS were assessed as mean (SD) and median (IQR), and for individual and super dimension scores (AQoL-8D), they were assessed as mean (SD).

A minimal clinically important difference or minimal important difference is the smallest difference in score in the outcome of interest which patients perceive as beneficial and which would mandate a change in the patient's management [46, 47]. A recently reported composite minimal important difference for the EQ-5D-5L of selected chronic health conditions including hypertension, heart disease, arthritis, asthma or chronic obstructive pulmonary disease, cancer, diabetes, chronic back pain, and anxiety or depression has been calculated as 0.04 utility points [35].

We adopted this recent EQ-5D-5L composite measure for our study because of the array of complex physical and psychosocial health conditions included in the measure of minimal important difference. There is no reported minimal important difference for the AQoL-8D; however, there is a reported minimal important difference for the AQoL-4D. This is a composite measure that also includes chronic health conditions [37]. We therefore conservatively reported a minimal important difference for the AQoL-8D as the upper bound of the confidence interval (CI) of the AQoL-4D's minimal important difference (95% CI: 0.03–0.08), namely, 0.08 points [37].

AQoL-8D Australian population norms for the total population and the 45- to 54-year-old age group were sourced from recently derived and published norms for the instrument [48].

Given that the MAUI-generated data are not normally distributed and also the relatively small sample size, this study employed the Wilcoxon signed rank test to test for statistical significance at the 5% level ($p<0.05$). The Wilcoxon signed rank test for significance is the nonparametric counterpart of the paired t test, and corresponds to a test of whether the median of the differences between paired observations is zero in the population from which the sample is drawn [49].

We undertook sensitivity analyses on the subgroup of individuals who fully completed both MAUIs' questionnaires for all three reported time points (called 'full-completers') to test the robustness of all results including significance testing.

Statistical analyses were undertaken using IBM SPPS (version 22) or R (version 3.0.2).

4.3 Results

4.3.1 Participants' clinical and socio-demographic characteristics and questionnaire completion

Twenty-three participants were recruited to the study and completed at least one of the MAUIs' questionnaires at one of the reportable time points to enable the generation of utility valuations (both instruments) and individual and super dimension scores (AQoL-8D only) (Table 2).

For these participants (n = 23), mean (SD) age was 50 (10) years, 43% were males, and mean (SD) time on the public waiting list for bariatric surgery was 6.5 (2.0) years. Table 2 (supported by Appendix) also provides results regarding changes in BMI, percentage total weight lost, and percentage excess weight lost. At 1 year postoperatively, the percentage of total weight lost was mean (SD) 16% (7.1%). BMI decreased from mean (SD) 49.3 (9.3) kg/m before surgery to 43.5 (7.2) (3 months) to 40.8 (7.0) (1 year) after surgery, giving rise to a significant reduction of 8.5 BMI units preoperatively to 1 year postoperatively ($p = 0.02$).

Appendix provides the socio-demographic characteristics of all participants (n = 23), the subgroup of full-completers of both questionnaires at all three reportable time points (n = 9), and the subgroup of participants who did not fully complete all questionnaires at the three reportable time points (n = 14). There was no substantial difference in age or sex [all participants (n = 23) males 43%; full-completers (n = 9) males 44%; partial-completers (n = 14) males 42%]. The order of magnitude for the number of years on the public waiting list was also similar. The postoperative obesity classifications and mean (SD) BMI measures were similar between the subgroups, and the magnitudes of change between obesity classifications were also similar between the subgroups.

Questionnaire completion for the entire cohort across the three reported time points is outlined in detail in Table 2. Overall, utility valuations could be assessed for 75% (103/138) of participants for both MAUIs across all time points, and for the individual and super dimension scores for the AQoL-8D. Additionally, there was a 67% completion rate at baseline (31/46) and a 76% (35/46) completion rate at 1 year. Subgroup analyses were conducted for full-completers of both instruments' questionnaires across all three time points (n = 9) (outlined below and Tables 2 and 3).

4.3.2 Changes in both instruments utility valuations compared to BMI

Table 2 provides summary results for changes in BMI, utility valuations (both instruments), and EQ-VAS scores at the three reported time points. Figure 1 also provides a schematic representation of utility changes for the entire cohort (n = 23) and full-completers (n = 9). Figure 2 provides the distribution of utility valuations at the individual level for both instruments (Fig. 2a EQ-5D-5L and Fig. 2b AQoL-8D) 1 year after surgery.

Our study's key finding was that change in both instruments' summary utility valuations and also the EQ-VAS scores reported clinical improvements that exceeded the minimal important difference for all participants (n = 23) (EQ-5D-5L 0.08 utility points; AQoL-8D 0.16 utility points; EQ-VAS 16 points) from before surgery to 1 year after surgery. Importantly, the change in utility valuations derived for the AQoL-8D was twice that for the EQ-5D-5L (0.16 vs. 0.08 utility points) for the 1-year time horizon. Further, the AQoL-8D utility change from baseline to 1 year was statistically significant ($p = 0.04$), whereas only a trend was observed for the EQ-5D-5L ($p = 0.25$) (Table 2; Fig. 1). When we compared preoperative versus 1-year postoperative utility increases to BMI reductions over the same time horizon, we found that for every 1.0-unit reduction in BMI, the AQoL-8D utility valuation increased 0.02 units, compared with a 0.01 increase in utility for the EQ-5D-5L.

Another important finding was that from 3 months to 1 year postoperatively, the mean EQ-5D-5L utility valuation showed a slight decrease, by 0.02 utility points, whereas the mean AQoL-8D utility valuation gave rise to the third of the identified increases in utility for this instrument across the three time points (+0.06 utility points). An increase was also observed in the EQ-VAS scores from 3 months to 1 year. Notwithstanding these general trends, all changes from the reported 3 months to 1 year time point were not statistically significant (Table 2).

After surgery, utility valuations at the individual level for both instruments were not normally distributed and the AQoL-8D revealed a wider dispersion (Fig. 2).

Subgroup analyses revealed that the orders of magnitudes, general trends, and significance testing of all our findings were robust when only the full-completers (n = 9) were analysed (Tables 2, 3). For example, from before surgery to 1 year after surgery, we found that the AQoL-8D's improvement in utility score 1 year after surgery was 0.15 points and the BMI reduction was 8.0 BMI units as compared with 0.16 utility points and a BMI reduction of 8.5 BMI units for the entire cohort (Tables 2 and 3).

Table 2: Comparison of study participants (total participants n = 23) BMI, summary health state utility valuations for the EQ-5D-5L and the AQoL-8D, and EQ-VAS scores before and 3 months and 1 year after bariatric surgery, and sensitivity analyses for full completers (n = 9).

(n=23)	Before surgery	3 months after surgery	1 year after surgery	Change in mean from 3 months to 1 year after surgery and ToS**(*p*≤0.05)	Change in mean from before surgery to 1 year after surgery and ToS** (*p*≤0.05)
Years on public waiting list *Mean (SD)*	6.5 (2.0) †				
BMI (kg/m²) *Mean (SD)*	(n=21) 49.3 (9.3)*	(n=21) 43.5 (7.2)	(n=22) 40.8 (7.0)	-2.7 BMI points *p*=0.40	- 8.5 BMI points *p*=0.02**
%TWL *Mean (SD)*	NA	NA	16% (7.1)	NA	16%
%EWL *Mean (SD)*	NA	NA	34% (14.9)	NA	34%
MAUIs' HSUVs and EQ-VAS scores (n=x)	Before surgery	3 months after surgery	1 year after surgery	Change in mean from 3 months to 1 year after surgery and ToS**(*p*≤0.05)	Change in mean from before surgery to 1 year after surgery and ToS** (*p*≤0.05)
EQ-5D-5L *Mean (SD)*	(n=16) 0.70 (0.25)	(n=19) 0.80 (0.25)	(n=18) 0.78 (0.25)	- 0.02 utility points *p*=0.92	+0.08 utility points *p*=0.25
Median (IQR)	0.73 (0.54 - 0.91)	0.84 (0.59 – 0.86)	0.86 (0.67 – 0.93)		
AQoL-8D *Mean (SD)*	(n=15) 0.51 (0.24)	(n=18) 0.61 (0.24)	(n=17) 0.67 (0.23)	+0.60 utility points *p=0.66*	+0.16 utility points *p*=0.04**
Median (IQR)	0.51 (0.29 – 0.78)	0.58 (0.43 – 0.78)	0.67 (0.48 – 0.86)		
EQ-VAS *Mean (SD)*	(n=16) 57 (25)	(n=19) 67 (24)	(n=18) 73 (19)	+6 points *p*=0.31	+16 VAS score *p*=0.08
Median (IQR)	65 (34 – 73)	65 (48 – 90)	80 (56 – 90)		
Sub group analysis* (n=9)	Before surgery	Three months after surgery	One year after surgery	Change in mean from 3 months to 1 year after surgery and ToS**(*p*≤0.05)	Change in mean from before surgery to 1 year after surgery and ToS** (*p*≤0.05)
BMI (kg/m²) *Mean (SD)*	47.6 (7.4)	43.6 (6.1)	39.6 (6.4)	4.0 BMI points	-8.0 BMI points
%TWL *Mean (SD)*	NA	NA	16.6% (7.3)	NA	16.6 %
%EWL *Mean (SD)*	NA	NA	36.3% (15.8)	NA	36.3 %
EQ-5D-5L utility *Mean (SD)*	0.69 (0.21)	0.80 (0.15)	0.73 0.20)	-0.07 utility points *p* =0.52	+0.04 utility points *p* =0.26
AQoL-8D utility *Mean (SD)*	0.45 (0.19)	0.57 (0.21)†	0.60 (0.22)	+0.03 utility points *p* =0.07	+0.15 utility points *p*=0.01**
EQ-VAS *Mean (SD)*	59 (22)	66 (22)	67 (21)	+1 VAS score	+ 8 VAS score *p* =0.18

BMI, body mass index; EWL, excess weight lost; HSUV, health state utility value; IQR, inter-quartile range; MAUI, multi-attribute utility instrument; NA, not applicable; SD, standard deviation; ToS, test of significance, TWL, total weight lost; VAS, visual analogue scale.
† One long-term waitlisted patient's time on the waiting list not available; * Full-completers subgroup analysis before and 3 months and 1 year after bariatric surgery; ** ToS Wilcoxon rank test (p≤0.05).

Table 3: Comparison of AqoL-8D individual and super dimension scores before and 3 months and 1 year after surgery (total participants, n = 23), Australian population norms an subgroup (sensitivity analysis).

(n=23)	Before surgery (n=15) mean (SD)	Three months after surgery (n=18)	One year After surgery (n=17)	Improvement in mean score preoperatively to 3 months and 1 year postoperatively.	Australian population norms		Subgroup (sensitivity) analysis (n=9)		
					45 – 54 year age group	Total	Before surgery	One year after surgery	Test of significance* ($p \leq 0.05$)
AQoL-8D individual and super-dimensions ***Individual dimensions of physical health***									
Independent Living	0.69 (0.22)	0.75 (0.19)	0.79 (0.20)	+0.06; 0.10	0.93 (0.12)	0.94 (0.11)	0.65 (0.20)	0.73 (0.21)	*p*=0.14
Senses	0.81 (0.13)	0.83 (0.13)	0.84 (0.11)	+0.02; 0.03	0.88 (0.10)	0.91 (0.10)	0.81 (0.14)	0.86 (0.12)	*p*=0.29
Pain	0.56 (0.34)	0.62 (0.32)	0.67 (0.31)	+0.06; 0.11	0.84 (0.21)	0.86 (0.19)	0.51 (0.31)	0.61 (0.30)	*p*=0.22
Individual dimensions of psychosocial health									
Happiness	0.65 (0.16)	0.75 (0.15)	0.77 (0.13)	+0.10; 0.12	0.77 (0.16)	0.80 (0.15)	0.61 (0.16)	0.76 (0.11)	*p*=0.01**
Coping	0.67 (0.15)	0.76 (0.15)	0.79 (0.12)	+0.09; 0.12	0.80 (0.16)	0.83 (0.15)	0.62 (0.10)	0.78 (0.09)	*p*=0.01**
Relationships	0.62 (0.16)	0.67 (0.18)	0.71 (0.18)	+0.05; 0.09	0.78 (0.16)	0.79 (0.16)	0.59 (0.17)	0.66 (0.16)	*p*=0.08
Self-worth	0.65 (0.21)	0.76 (0.18)	0.75 (0.19)	+0.11; 0.10	0.84 (0.16)	0.85 (0.15)	0.73 (0.19)	0.73 (0.18)	*p*=0.03**
Mental Health	0.54 (0.12)	0.60 (0.15)	0.62 (0.19)	+0.06; 0.08	0.67 (0.17)	0.69 (0.17)	0.53 (0.09)	0.59 (0.18)	*p*=0.25
Super dimensions									
Physical super dimension	0.51 (0.29)	0.56 (0.27)	0.62 (0.26)	+0.05; 0.11	0.79 (0.20)	0.83 (0.18)	0.46 (0.27)	0.55 (0.24)	*p*=0.13
Psychosocial super dimension	0.25 (0.15)	0.37 (0.25)	0.41 (0.25)	+0.12; 0.16	0.47 (0.24)	0.50 (0.24)	0.20 (0.11)	0.34 (0.23)	*p*=0.008**
HSUV	0.51 (0.24)	0.61 (0.24)	0.67 (0.23)	+0.10; 0.16	0.77 (0.20)	0.80 (0.19)	0.45 (0.19)	0.60 (0.22)	*p*=0.01**

HSUV, health state utility valuation;
* Wilcoxon signed rank test significant at $p \leq 0.05$
** Significant result at ($p < 0.05$)

Figure 1: Comparison of the EQ-5D-5L and AqoL-8D health state utility valuations before surgery and 3 months and 1 year after surgery.

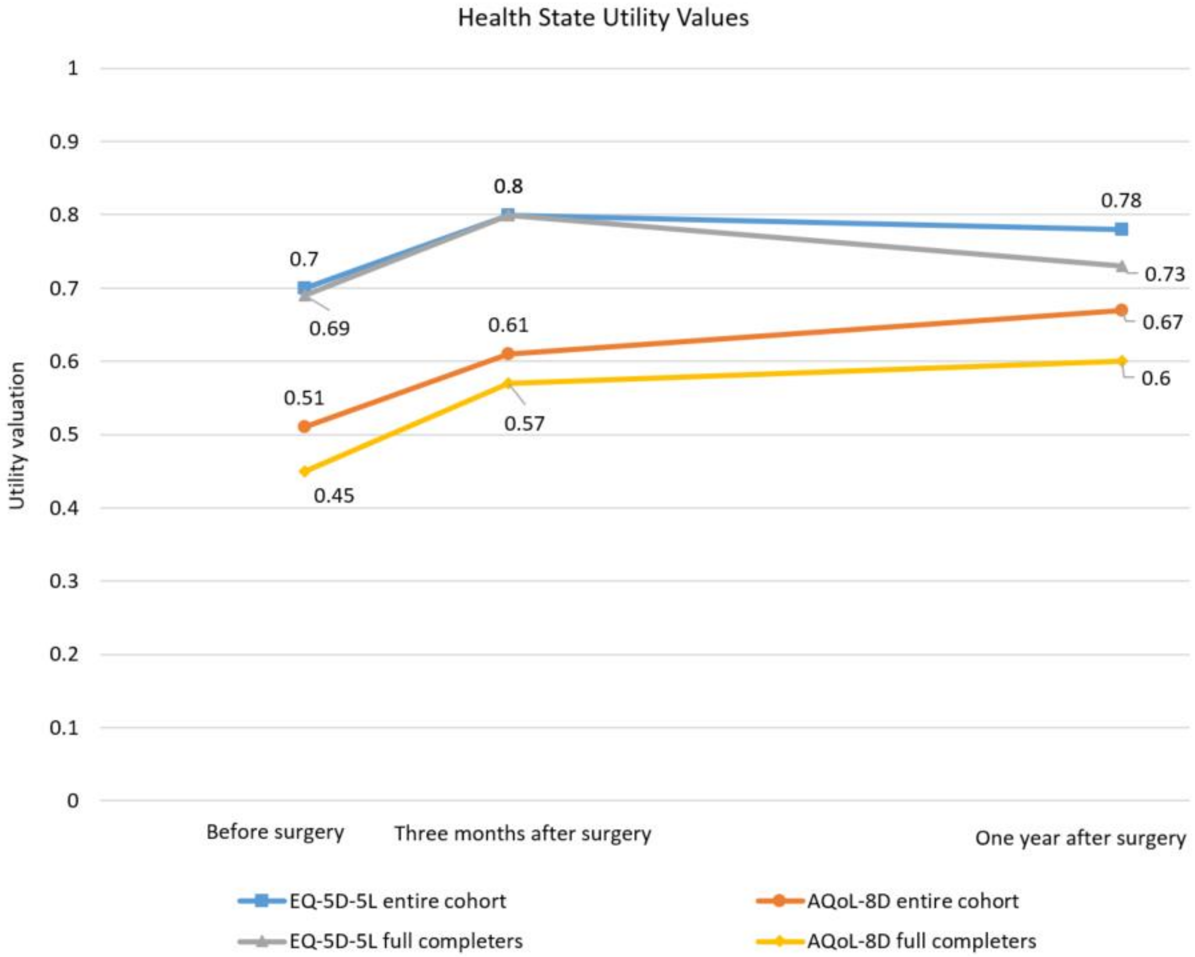
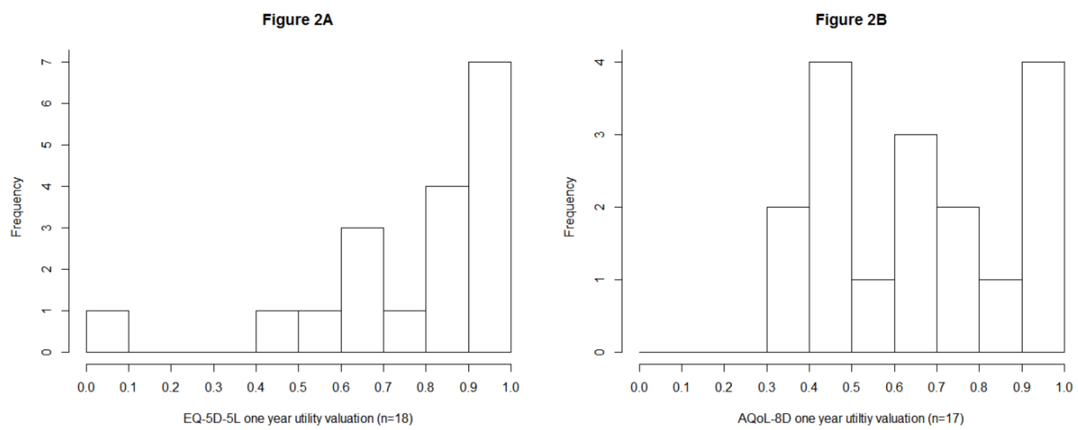


Figure 2: Frequency distributions of utility valuations at the individual level for the EQ-5D-5L (n = 18) (a); and AQ-l-8D (n = 17) (b) for the entire cohort 1 year after bariatric surgery.



4.3.3 Assessment of individual domains of HRQoL: AQoL-8D individual and super dimension scores

Table 3 provides a comparison of the AQoL-8D's individual dimensions (Independent Living, Senses, Pain, Happiness, Coping, Self-worth, Relationships, and Mental Health) and Physical and Psychosocial super dimensions for the three reported time points, and subgroup analyses and significance testing for the full-completers subgroup from before surgery to 1 year after surgery.

A key finding for our particular study population of long-term waitlisted patients a year after bariatric surgery was that all individual and super dimension scores within the AQoL-8D improved. The individual psychosocial dimensions of Happiness, Coping, and Self-worth improved the most over this time horizon (0.12, 0.12, and 0.10 point improvements, respectively). The individual physical dimensions of Independent Living and Pain also improved (0.10 and 0.11 points, respectively). Additionally, Happiness and Coping approached general population norms [48]. These results were robust to subgroup analysis of full-completers of all three questionnaires (Table 3). Importantly, significance testing of the full-completers' results revealed that Happiness ($p = 0.01$), Coping ($p = 0.01$), Self-worth ($p = 0.03$), and the Psychosocial super dimension ($p = 0.008$), and the summary AQoL-8D utility valuation ($p = 0.01$) were statistically significant (Table 3).

4.4 Discussion

Our exploratory study is the first study to investigate the HRQoL impacts using both the EQ-5D-5L and AQoL-8D for a study population of severely obese, long-term publicly waitlisted patients who were then able to access bariatric surgery in 2015 because of a 2014 State

Government public policy decision to reduce waiting times and to surgically treat long-waiting patients.

Our exploratory study suggested that the participants' responses to the EQ-5D-5L and AQoL-8D (76% response rate at 1 year of n=18 EQ-5D-5L) and n=17 (AQoL-8D)) generated clinical improvements in utility valuations and EQ-VAS scores from before surgery to 1 year after surgery (EQ-5D-5L utility valuation from 0.70 to 0.78; AQoL-8D 0.51 to 0.67), where the minimal important differences were exceeded.

Another important finding was that the AQoL-8D's increase in utility valuation (0.16 utility points) was twice that of the EQ-5D-5L increase (0.08 utility points) at 1 year, with the AQoL-8D result statistically significant (and robust to subgroup analyses of the full-completers), albeit, for a small and exploratory cohort of long term publicly waitlisted patients who underwent bariatric surgery due to a public policy decision to reduce waiting lists.

4.4.1 Public resource allocation to bariatric surgery: waiting lists and patient prioritisation

Our exploratory study's key findings highlighted two important and inextricably linked points regarding the assessment and utilisation of utility valuations for long-term waitlisted patients who subsequently undergo bariatric surgery. First, choice of an appropriate MAUI to preferentially capture and assess HRQoL for this study population is crucial. Second, suboptimal public resource allocation decisions regarding the 'optimal' amount of bariatric surgery will likely occur if utility valuations, as an input measure of health impact for health economic evaluation (specifically cost-utility analyses), are generated by an instrument that is not sensitive to this study population's complex HRQoL.

Health economic evaluation is an important resource allocation methodology because it provides decision-makers with comparable analyses to underpin decisions about committing scarce healthcare resources to one use instead of another [14]. Cost-utility analyses of bariatric surgery to date have been dominated by use of the EQ-5D MAUIs [14]. Economic evaluation of interventions which affect HRQoL commonly employ cost-utility analyses which prioritise interventions according to the cost per quality-adjusted life-year. The estimation of quality-adjusted life-years is increasingly based upon the utility valuations predicted from an MAUI [50]. One of our exploratory study's key findings was that the AQoL-8D's utility changes/impacts from before surgery to 1 year after surgery were twice the magnitude of the EQ-5D-5L. Additionally, the EQ-5D-5L reported a plateauing utility valuation from 3 months to 1 year, in contrast to the AQoL-8D, which revealed a clinical improvement. If the nominated instrument lacks sensitivity within a particular health context (or health domain), interventions (such as bariatric surgery) affecting health states where the chosen instrument's sensitivity is low, will likely be disadvantaged [24, 50].

A recent study that investigated EQ-5D-5L utility valuations for patients who had undergone surgery at a Canadian Bariatric Centre for Excellence (n = 304 before surgery, n = 138 after surgery, 45% completion rate after surgery) found that mean utility valuation before and 1 year after surgery was 0.65 (before)/0.90 (after) utility points (for 'other' bariatric surgery) and 0.70 (before)/0.90 (after) utility points (for Roux-en-Y bariatric surgery) [51]. These results are similar to the order of magnitude of our exploratory study's EQ-5D-5L preoperative results. We note that the higher postoperative valuation for the Canadian study could be explained by the use of the Candadian scoring algorithm was used, or the low completion rate, arguably of patients who would rate themselves closer to perfect health (45% of patients only responding 1 year postoperatively), and the EQ-5D-5L's inability to detect health impacts closer to perfect health (ceiling effects).

In contrast, our study's AQoL-8D preoperative summary utility valuations of mean (SD) 0.51 (0.24) indicated a significantly diminished HRQoL for our study population before surgery that was also reflected in the AQoL 8D's individual and super dimension scores. In turn, the AQoL-8D's ability to preferentially capture HRQoL (compared with the EQ-5D-5L) for our study population of long-term waitlisted patients who then subsequently underwent bariatric surgery is reflected in the reduced utility valuations.

One of the key findings of our earlier research that conducted a head-to-head comparison of the two instruments was that the EQ-5D-5L and AQoL-8D are not interchangeable for people who had undergone bariatric surgery many years previously [24]. This study of long-term waitlisted patients also suggests that the AQoL-8D preferentially captures HRQoL and that the two instruments are not interchangeable for long-term waitlisted patients who subsequently undergo bariatric surgery.

Recent evidence has found that utility valuations measured by the major MAUIs differ [namely, the EQ-5D-5L, SF-6D, Health Utilities Index (HUI) 3, 15D and AQoL-8D] [50]. Most of these differences can be explained by the descriptive/classification systems of the MAUIs. These 'dominating' differences are estimated to explain an average of 66% of the difference between utilities obtained by the MAUIs (i.e. EQ-5D-5L, SF-6D, HUI 3, 15D, and AQoL-8D) and 81% of the difference between the utilities of the EQ-5D-5L and AQoL-8D [50]. In turn, our study's findings reflect the relative sensitivities of the EQ-5D-5L's and AQoL-8D's classification systems to our study population's physical and psychosocial domains of health. The AQoL-8D's changes in utility valuation were predominantly driven by the AQoL-8D's individual psychosocial dimensions and Psychosocial super dimension scores.

The AQoL-8D's utility valuations differed significantly from before surgery to 1 year after surgery, predominantly driven by the AQoL-8D's individual psychosocial and Psychosocial super dimension scores. Cost-utility analyses of the health impacts for long-term waitlisted patients who subsequently undergo bariatric surgery should appropriately reflect these health impacts. Our findings are particularly important because cost-utility analyses of bariatric surgery are dominated by the EQ-5D MAUIs [14].

In summary, long-term publicly waitlisted patients are an important and emerging subgroup of bariatric surgery patients, yet there is a paucity of evidence regarding longitudinal HRQoL impacts for this population if they are successful in getting publicly funded bariatric surgery. Our findings show that previously long-waiting patients with substantially diminished HRQoL did show significant improvements in HRQoL after surgery. This is important in that it shows clearly that long-waiting patients should not be 'written off'—they can still realise significant improvements in HRQoL outcome when ultimately treated. A recent cost-utility study from Sweden, the first study to quantify the potential impact of extensive waiting times on the costs and clinical outcomes of bariatric surgery, highlighted the necessity of reducing waiting lists and removing unnecessary barriers to allow greater utilisation of surgery for patients unresponsive to conservative medical management [10]. Nevertheless, addressing this issue, given the large gap between the demand for and supply of publicly funded bariatric surgery, which has resulted in protracted wait times for the procedure in countries such as Australia, Canada, and the UK [17, 52] and the longest of any surgical procedure in Canada (average 5 years) [17], would require significant commitment and investment.

4.4.2 Weight status is only one factor contributing to complex HRQoL for long-term waitlisted patients who undergo bariatric surgery

Another important finding of our study is that the AQoL-8D's individual and super dimension scores identify psychosocial health as an important driver of holistic postoperative health 1 year after bariatric surgery. The AQoL-8D's Psychosocial super dimension almost doubled in magnitude from before surgery to 1 year after surgery, and this change was statistically significant. This result is validated by a recent systematic review of the literature regarding the quality-of-life outcomes of bariatric surgery, where the SF-36 was the most commonly used HRQoL instrument and the quality-of-life subscale for mental health showed improvements in three of the six included SF-36 studies [25]. Notably, none of these studies generated utility valuations or scores. Our study's AQoL-8D Psychosocial super dimension result is also validated by recent literature which suggests that psychosocial health status increases up to 4 years after bariatric surgery, but declines after this timeframe [22, 23]. Utility valuations have also been found to be independent predictors of health impacts [44]. Our study's results also support our earlier findings that if the choice of MAUI appropriately captures the individual and study population's physical and psychosocial health status through the sensitivity of the MAUI's dimensions/classification system, then the MAUI's predictive qualities could be a useful clinical measurement tool to rapidly and conveniently assess the intervention's likely health impacts in individuals and for the study population [24].

Our study also found that relative to BMI unit reductions, the AQoL-8D recorded 0.02-utility point increases for 1.0-BMI unit reductions, and for the EQ-5D-5L, 0.01- utility point increases for 1.0-BMI unit reductions. A recent study found that for the EQ-5D-3L, for a 1.0-unit BMI reduction there was a 0.0051–0.0075 increase in utility. Notwithstanding the differing classification systems and utility valuations of the two MAUIs, the AQoL-8D recorded a greater utility increase per unit of BMI reduction. We contend that this difference was driven by the impact of psychosocial health—the AQoL-8D's broader (depth and breadth) psychosocial classification system captured and assessed domains of health that are not 'weight change' or 'BMI change' related. Our findings are also supported by a recent cross-sectional study that compared quality of life measured by the Moorehead–Ardelt Quality of Life Questionnaire in obese patients 12–18 months after bariatric surgery that found there is a limited relationship between BMI and HRQoL [42].

In summary, we contend that the importance of psychosocial factors in driving the measured improvements in HRQoL should not be lost on policy-makers in allocating resources. Much recent debate on bariatric surgery has focused on the physical health impacts of weight loss, especially on its potential to avoid or mitigate the worst effects of diabetes. However, if much of the real health gain observed derives from psychosocial impacts, this may have important consequences for patient selection and prioritisation decisions.

4.4.3 Increased mobility

We also found that the AQoL-8D's individual physical dimensions of Independent Living and Pain improved from before surgery to 1 year after surgery. A recent study that conducted proportional analysis for the EQ-5D 5L has found that mobility significantly increases 1 year after bariatric surgery [51]. The increases in the AQoL-8D individual physical dimensions of health and the Physical super dimension further support these findings.

Only 10 of the 35 items of the AQoL-8D capture and assess the physical domains of health that inform the individual physical dimensions of Independent Living, Senses, and Pain. A recent study suggests that the AQoL-8D's descriptive system is preferential to psychosocial health rather than physical health [53].

4.4.4 Supporting qualitative evidence

Some of our study's participants participated in long interviews for an associated qualitative study regarding the support needs of patients waiting for publicly funded bariatric surgery [18]. The findings of this study indicated that waiting for bariatric surgery was commonly associated with a range of deleterious consequences including weight gain and deteriorating physical and psychosocial health [18]. These qualitative findings both support and provide further contextualisation and nuance to our study's baseline AQoL-8D utility valuations and individual and Psychosocial and Physical super dimension scores that revealed substantially reduced summary utility valuations and scores that were well below the relative Australian population norms (Table 3). Our study has shown that our cohort's HRQoL was substantially diminished before surgery, and this qualitative evidence also suggests it is likely that utility valuations and individual and super dimension scores could have been measurably lower for our unique cohort if long-waiting patients were left untreated.

4.4.5 Limitations

There are a number of limitations to our study. The first limitation is sample size. Nevertheless, our study was exploratory and we were provided with a novel opportunity to recruit participants from the long-term waitlisted patients subsequently fast-tracked for bariatric surgery through a government policy decision to reduce waiting lists. The second limitation is that all participants were operated on by the same surgeon in the same hospital. This could affect the generalisability of our results if scaled up to all bariatric surgery patients. The third limitation is that there is no control arm in the study. The observational nature of our study did not enable the recruitment of a control arm to elicit utility valuations. The fourth limitation is the use of the UK value set for the EQ-5D-5L because there is no Australian value set available for the instrument. A fifth limitation is that overall, 25% of partcipants did not respond to the survery instruments suggesting that there could be a non-response bias particularly given the size of the study sample. The final limitation is that the sample is also at risk of participant selection bias, which could also affect the generalisability of our results. Recent evidence has found that public sector waiting times are years in duration in some countries and that there are physical (worsening of comorbidities and further weight gain) and psychosocial impacts for patients waiting for bariatric surgery.

A strength of our study is the high response rate of 75% to the questionnaires across all three reportable time points. Additionally, our study is an exploratory study of long-term waitlisted patients and could inform larger confirmatory studies of HRQoL (particularly assessed through utilities derived from generic MAUIs) for long-term waitlisted patients who subsequently undergo bariatric surgery.

4.5 Conclusions

Our exploratory study of long-term waitlisted patients recruited opportunistically following a government policy decision to reduce waiting lists suggests that long-waiting bariatric surgery patients should not be 'written off' by healthcare planners; they can still realise significant improvements in HRQoL outcomes when ultimately treated, and this should be factored into patient prioritisation decisions. Addressing this issue given the large gap between the demand for and supply of publicly funded bariatric surgery in many countries would require significant commitment and investment.

Ongoing improvements in psychosocial parameters from 3 months to a year post-surgery explained improvements in overall utility valuation measured by the AQoL-8D that were not detected by EQ-5D-5L. Selection of a sensitive instrument is crucial to adequately measure changes in utility valuation and to accurately reflect changes in quality-adjusted life-years generated for cost-utility analyses. Cost-utility analyses for long term waitlisted patients for bariatric surgery should employ utility valuations from MAUIs that are sensitive to physical and psychosocial health changes. Only through comprehensive assessments of HRQoL impacts before and after surgery can we robustly inform public resource allocation decisions. We found that the AQoL-8D preferentially captures these health impacts compared with the EQ-5D-5L. Nevertheless, we also suggest that a larger confirmatory multi-centre study would be appropriate to test the findings of our exploratory single-centre study.

Coupled with BMI assessment, pre-surgery utility valuations should be investigated as independent predictors of post-surgery HRQoL (particularly psychosocial health status) for morbidly obese, long-term waitlisted, bariatric surgery patients.

Appendix

Appendix: Participants' clinical and socio-demographic characteristics before and 1 year after surgery for the total fast-track cohort, the subgroup of participants who fully completed both MAUIs at all 3 time points, and the subgroup of participants who were not full completers (n = 14).

Characteristics	**Fast track cohort** (n=23)	**Full-completers** (n=9)	**Partial completers** (n=14)
Age years			
Mean (SD)	50 (10)	48 (11)	52 (9)
Sex			
(n = x, %)	Male (10, 43 %) Female (13, 57 %)	Male (4, 44 %) Female (5, 56 %)	Male (6, 42 %) Female (8, 58 %)
Number of years on public waiting list			
Mean (SD)	6.5 (2.0) **	7.3 (2.5)	6.1 (1.6)
Number of participants in obesity category (n = x, %)			
Before surgery			
BMI ≥ 30 – 34.9 kg/m^2 (Class I)	(1, 4 %)	0	(1, 7 %)
BMI ≥ 35 – 39.9 kg/m^2 (Class II)	0	0	0
BMI ≥ 40 – 49.9 kg/m^2 (Class III)	(13, 57 %)	(7, 78 %)	(6, 43 %)
BMI ≥ 50 kg/m^2 *	(9, 39 %)	(2, 11 %)	(7, 50 %)
12 months after surgery			
BMI ≥ 30 – 34.9 kg/m^2 (Class I)	(2, 10 %)	(2, 14 %)	(3, 21 %) †
BMI ≥ 35 – 39.9 kg/m^2 (Class II)	(7, 33 %)	(3, 21 %)	(2, 14 %)
BMI ≥ 40 – 49.9 kg/m^2 (Class III)	(9, 43 %)	(3, 21 %)	(6, 43 %%)
BMI ≥ 50 kg/m^2	(3, 14 %)	(1, 11 %)	(2, 14 %%)
BMI (kg/m^2)			
Before surgery			
Mean (SD)	49.3 (9.35)	47.6 (7.4)	49.9 (10.6)
After surgery			
Mean (SD)	43.5 (7.17)	39.6 (6.4)	41.6 (7.5) †
% Total weight lost			
Mean (SD)	16 (7.1)	NA	NA

4.6 References

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Appendix 4A: Publication of "An exploratory study of long-term publicly waitlisted bariatric surgery patients' quality of life before and 1 year after bariatric surgery, and considerations for healthcare planners".

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ORIGINAL RESEARCH ARTICLE

An Exploratory Study of Long-Term Publicly Waitlisted Bariatric Surgery Patients' Quality of Life Before and 1 Year After Bariatric Surgery, and Considerations for Healthcare Planners

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Abstract

Background Long-term publicly waitlisted bariatric surgery patients typically experience debilitating physical/psychosocial obesity-related comorbidities that profoundly affect their quality of life.

Objectives We sought to measure quality-of-life impacts in a study population of severely obese patients who had multiyear waitlist times and then underwent bariatric surgery.

Methods Participants were recruited opportunistically following a government-funded initiative to provide bariatric surgery to morbidly obese long-term waitlisted patients. Participants self-completed the EQ-5D-5L and AQoL-8D questionnaires pre- and postoperatively. Utility valuations (utilities) and individual/super dimension scores (AQoL-8D only) were generated.

Results Participants' ($n = 23$) waitlisted time was mean [standard deviation (SD)] 6.5 (2) years, body mass index reduced from 49.3 (9.35) kg/m^2 preoperatively to 40.8 (7.01) 1 year postoperatively ($p = 0.02$). One year utilities revealed clinical improvements (both instruments). AQoL-8D improved significantly from baseline to 1 year, with the change twice that of the EQ-5D-5L [EQ-5D-5L: mean (SD) 0.70 (0.25) to 0.78 (0.25); AQoL-8D: 0.51 (0.24) to 0.67 (0.23), $p = 0.04$], despite the AQoL-8D's narrower algorithmic range. EQ-5D-5L utility plateaued from 3 months to 1 year. AQoL-8D 1-year utility improvements were driven by Happiness/Coping/Self-worth ($p < 0.05$), and the Psychosocial super dimension score almost doubled at 1 year ($p < 0.05$). AQoL-8D revealed a wider dispersion of individual utilities.

Conclusions Ongoing improvements in psychosocial parameters from 3 months to 1 year post-surgery accounted for improvements in overall utilities measured by the AQoL-8D that were not detected by EQ-5D-5L. Selection of a sensitive instrument is important to adequately assess changes in quality of life and to accurately reflect changes in quality-adjusted life-years for cost-utility analyses and resource allocation in a public healthcare resource-constrained environment.

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Key Points for Decision Makers

Psychosocial health status is an important health-related quality-of-life (HRQoL) outcome for long-waiting bariatric surgery patients. Whilst the EQ-5D is prevalent in the economic evaluation of bariatric surgery, compared with the EQ-5D-5L, the AQoL-8D preferentially captures and assesses psychosocial health for this study population.

If used in the clinical setting, utility valuations and individual and super dimension scores could provide both clinicians and healthcare decision-makers with important information regarding HRQoL impacts for people who have waited many years in the public health system for their bariatric surgery.

Long-waiting bariatric patients should not be 'written-off' by healthcare planners; they can still realise significant improvements in HRQoL outcomes when ultimately treated, and this should be factored into patient prioritisation decisions.

1 Introduction

Obesity is a profoundly complex global public health, economic, and strategic policy problem [1–5]. Bariatric (obesity or metabolic) surgery is generally considered the most efficacious and cost-effective treatment intervention for people with intractable severe or morbid obesity, particularly for subgroups of patients such as people with type 2 diabetes [6–13]. Nonetheless, a recent comprehensive systematic review of 77 diverse health economics studies that reported on bariatric surgery from 1995 to 2015 found the EQ-5D is the prevalent multi-attribute utility instrument (MAUI) used in cost-utility analyses of bariatric surgery worldwide, and the impact of time delay for publicly waitlisted patients on the clinical, quality-of-life, and economic outcomes of bariatric surgery has been largely ignored [14].

As an important subgroup of bariatric surgery patients, long-term morbidly obese, publicly waitlisted, bariatric surgery patients generally experience increased physical and psychosocial comorbidity loads that ultimately translate to 'sicker' patients demanding proportionally more of the scarce healthcare dollar [14–17]. Recent qualitative evidence has indicated that waiting for bariatric surgery can lead to development of new or worsening obesity-related comorbidity or decline in mobility and be emotionally challenging ('frustrating', 'depressing', 'stressful') [18]. Additionally, the need to assess the psychosocial health status of bariatric patients in the short, medium, and longer terms has been increasingly identified [19] and recognised as crucial for bariatric surgery patients [20–24]. Moreover, the psychosocial health status of bariatric surgery patients is dynamic, some studies suggesting an improvement up to 4 years and declining thereafter [22, 24]. Other studies suggest that quality of life significantly improves up to 1 year and is maintained at 2 years [25]. Importantly, there is a paucity of quantitative evidence concerning the health-related quality-of-life (HRQoL) impacts for the group of long-waiting, public healthcare patients who then undergo bariatric surgery.

Within resource-constrained healthcare budgets, funders' perceptions of 'affordability' are changing as bariatric surgery has increasingly become accepted as more than a cosmetic procedure for obesity and as the scale of the epidemic of severe obesity has become clearer [14]. Furthermore, the allocation of public-sector budgets is one part of a tremendously complex healthcare landscape that results in severely obese bariatric surgery candidates (with complex obesity-related comorbidities that translate to diminished HRQoL) experiencing multiyear wait times [14, 15]. A key reason for these multiyear wait times is the disproportionate rate of increase in severe obesity, and therefore the ever increasing demand for bariatric surgery surpassing the relatively static supply [17, 26].

Recent evidence has highlighted the differences and disagreements regarding the prioritisation of quality-of-life outcomes by health professionals and patients [27], revealing that patients prioritised seven quality of life items, none of which were prioritised by professionals. Surgeons prioritised only one quality-of-life outcome (versus four to 11 in the other health professionals' subgroups, e.g. nurses and dieticians) [27]. These findings highlight the importance of individual, self-reported patient assessments of HRQoL in the bariatric surgery population.

Standardised outcomes reporting guidelines for metabolic and bariatric surgery were developed by the American Society of Metabolic and Bariatric Surgeons (ASMBS) to drive consistency of reporting clinical and HRQoL outcomes within the field [20, 21]. These guidelines acknowledge that whilst bariatric surgery produces marked weight loss and improvement of physical comorbidities, the impact on HRQoL is less well established [20, 21]. The guidelines did not provide specific recommendations regarding the reporting of health state utility values, also described as utility valuations or utilities [24].

Utility valuations are important health economic metrics that assess the strength of preference for an individual's health state relative to perfect health and death, and importantly have inherent independent meaning [24, 28]. Utilities are assessed relative to a 0.00–1.00 scale, where 1.00 represents perfect health and 0.00 represents death, and therefore indicates the strength of preference for quality versus quantity of life [29]. Utilities are also a vital component of cost-utility analysis (a commonly used form of full economic evaluation that assesses the incremental costs of an intervention versus the incremental gains in quality-adjusted life-years) [12, 29, 30].

MAUIs are designed to rapidly and simply assess an individual or study population's utility valuation(s) through the application of pre-established formulae/weights to the array of patient-reported responses to the instrument's questions (generally self-reported through, for example, clinic visits, mail-outs, or the Internet) [24, 31, 32]. Based on patient-reported responses to MAUIs' questionnaires, the algorithm of a given instrument generates utility valuations. Many instruments generate utilities that are less than zero described as a health state perceived to be worse than death (e.g. the most recent EQ-5D-5L UK value set range: −0.281 to 1.0 [33, 34]). Most instruments report minimal clinically important differences or minimal important differences for their utilities [35–37].

The EQ-5D-5L is an internationally prevalent MAUI used in the assessment of patient-reported quality-of-life outcomes and full economic evaluations of treatment interventions (including bariatric surgery) [14, 38]. Recent evidence has suggested that for the EQ-5D-3L (precursor to the 5L), a 1.0-unit decrease in body mass index (BMI) is associated with a 0.0051- to 0.0075-utility point increase. For a 1.0-unit decrease in BMI, the study reported a 0.0051 increase in utility when adjusted for baseline presence of comorbidity (stepwise approach); a 0.0052 increase in utility when adjusted for age, sex, and baseline BMI; a 0.0068 increase in utility when adjusted for age, sex, baseline BMI, and baseline comorbidity; and a 0.0075 increase in utility associated with the primary (baseline) analysis [39].

The AQoL-8D MAUI is informed by psychometric principles and testing and has been found to preferentially capture psychosocial health for people who had already undergone bariatric surgery many years previously in the private healthcare system {median [interquartile range (IQR)] 5 (3–8) years} [24, 40, 41]. This study also found that the AQoL-8D and EQ-5D-5L instruments were not interchangeable for the study population and that body weight is just one factor contributing to the complex HRQoL [24]. A recent study that investigated cross-sectional quality-of-life data using the Moorehead–Ardelt Quality of Life Questionnaire II also found that quality of life after bariatric surgery is not just dependent on weight loss [42]. Nevertheless, the Moorehead–Ardelt Quality of Life Questionnaire II is not an MAUI.

Another recent study suggested that clear preoperative predictive markers of well-defined postoperative success following bariatric surgery would be invaluable and facilitate a more refined and evidence-based mechanism by which to select patients for bariatric surgery [43]. The study found that it is important to explore the relationships between preoperative clinical parameters and HRQoL in those morbidly obese patients who are eligible for bariatric surgery, and that identifying those clinical and psychosocial predictors of success assumes great significance when selecting (or prioritising) patients for bariatric surgery [43]. A recent systematic review that investigated quality-of-life outcomes for bariatric surgery patients found that the SF-36 was the most commonly used HRQoL instrument in the review's 13 included studies (control group was one of the inclusion criteria) [25]. Utility valuations were not generated in these studies [25]. Importantly, utility valuations have been shown to be independent predictors of patient outcomes in patients with type 2 diabetes, including all-cause mortality and development of complications [44]. Clinicians have also found that measuring utilities is of benefit to patient–clinical assessment, relationships, communication, and management [32].

Our study arose from a targeted State Government of Tasmania, Australia, policy decision to reduce Tasmanian public hospital surgical waiting lists. This initiative provided us with a novel and exploratory opportunity to recruit a cohort of morbidly obese, long-term waitlisted, bariatric surgery patients who then underwent bariatric surgery as a result of this policy initiative. This provided us with the opportunity to investigate an important and increasingly prevalent study population of bariatric surgery patients who inherently carry complex physical and psychosocial HRQoL needs. We aimed to investigate the physical and psychosocial HRQoL changes in these patients by using the EQ-5D-5L and AQoL-8D MAUIs to generate utility valuations (both instruments), and the AQoL-8D's individual dimensional scores (namely, Independent Living, Senses, Pain, Happiness, Coping, Relationships, Self-worth, and Mental Health) and super dimensional scores (namely, the composite Physical super dimension of Independent Living, Senses, and Pain; and the composite Psychosocial super dimension of Happiness, Coping, Relationships, Self-worth, and Mental Health) preoperatively and at two postoperative time points (namely, 3 months and 1 year). We also aimed to explore the HRQoL benefits of bariatric surgery for long-term waitlisted patients and concomitance with BMI changes. We further aimed to investigate whether the MAUIs would reveal significant psychosocial HRQoL impacts at 1 year postoperatively. We also aimed to explore whether utility valuations and individual and super dimension scores could provide healthcare decision-makers with important information regarding HRQoL impacts for people who had waited many years in the public health system for their bariatric surgery.

2 Methods

2.1 Study Design

2.1.1 Recruitment of Participants

A Tasmanian government policy decision was made in 2014 to allocate additional and targeted public funds to provide morbidly obese, long-term waitlisted patients with bariatric surgery in 2015. The policy decision provided us with an opportunity to recruit bariatric surgery patients who had waited for their surgery in a public healthcare system for many years. Appropriate ethics approvals were obtained from our University's Health and Medical Human Research Ethics Committee before commencement of our study's recruitment of participants.

We subsequently invited patients who were identified for bariatric surgery to participate in our study. Participants were provided an information package and consent materials before their bariatric surgery pre-admission clinic. The process for participants' questionnaire completion after consenting to participate in the study is outlined in Sect. 2.1.2.

Participants who consented to participate in our quality-of-life study underwent publicly funded laparoscopic adjustable gastric banding (LAGB) surgery by the same surgeon in the Hobart Private Hospital. Laparoscopic banding was carried out using Apollo APS or APL bands, with adjustment ports attached to the left anterior rectus sheath [45]. Postoperative fluid diets were maintained for 3 weeks, with subsequent transition to normal foods, accompanied by instruction on eating technique and exercise.

2.1.2 The Multi-attribute Utility Instruments and Questionnaire Completion

Our earlier study comparing the EQ-5D-5L and AQoL-8D MAUIs for people who had undergone LAGB surgery many years previously provided a detailed summary of the divergent characteristics of the two purposively selected MAUIs [24]. Table 1 provides an overview of these characteristics. In summary, the EQ-5D-5L is an internationally prevalent instrument (e.g. from 2005 to 2010, the EQ-5D was used in 63% of economic evaluations) [38]; the EQ-5D instrument is prevalent in the full economic evaluation of bariatric surgery [14]; it describes 3125 health states (compared with 243 health states of the EQ-5D-3L precursor to the 5L); four of the five instrument's health domains/classifications focus on physical HRQoL; and it takes less than 1 min to complete the EQ-5D-5L's questionnaire. The EQ-5D-5L also contains a visual analogue scale (EQ-VAS). In contrast, the AQoL-8D's classification system is supported by psychometric principles and testing, and 25 of the instrument's 35 items capture and assess five (from eight) psychosocial domains of health (Happiness,

Table 1 Comparison of the dimensions of the EQ-5D-5L and AQoL-8D multi-attribute utility instruments

Characteristics	EQ-5D-5L	AQoL-8D
Number of health states described	3125	2.4×10^{23}
Total number of dimensions	Five dimensions, 1 item in each. Each item has 5 levels of severity scored as 1 (best) to 5 (worst)	Eight dimensions of between 3 and 8 items; 35 items in total. 25 of the 35 items capture and assess psychosocial domains of health.
Number of dimensions of physical health	Four dimensions: mobility, self-care, usual activities, and pain/discomfort	Three dimensions: (1) Independent Living, 4 items (household tasks, getting around, mobility, self-care); (2) Senses, 3 items (vision, hearing, communication); and (3) Pain, 3 items (frequency of pain, degree of pain, pain interference)
Number of dimensions of psychosocial health	One dimension: anxiety/depression with five levels of severity: (1) I am not anxious or depressed (2) I am slightly anxious or depressed (3) I am moderately anxious or depressed (4) I am severely anxious or depressed (5) I am extremely anxious or depressed	Five dimensions: (4) Happiness, 4 items (contentment, enthusiasm, degree of feeling happiness, pleasure); (5) Coping, 3 items (energy, being in control, coping with problems); (6) Relationships, 7 items (relationship with family and friends, social isolation, social exclusion, intimate relationship, family role and community role); (7) Self-worth, 3 items (feeling like a burden, worthlessness, confidence); (8) Mental Health, 8 items (feelings of depression, trouble sleeping, feelings of anger, self-harm, feeling despair, worry, sadness, tranquillity/agitation)
Super dimensions of physical and psychosocial health	No super dimensions	Two super dimensions: Physical super dimension (PSD) and Psychosocial super dimension (MSD). PSD includes independent living, senses, and pain; MSD includes happiness, coping, relationships, self-worth, and mental health

Coping, Self-worth, Relationships, and Mental Health). The AQoL-8D describes billions of health states and takes 5 min to complete [40, 41].

Participants were asked to self-complete both instruments' questionnaires before their bariatric surgery at the pre-admission preoperative clinics and at two postoperative reportable time points, namely 3 months and 1 year after their bariatric surgery. Postoperative questionnaires were mailed out for self-completion with an explanatory cover letter and reply paid envelope enclosed. We evaluated the EQ-5D-5L and AQoL-8D questionnaire completion by assessing the overall proportion of participants who completed the questionnaire(s) at the study's three time points for whom an individual utility value could be generated (outlined in Sect. 2.2).

2.2 Data Analysis

Participants with patient-reported HRQoL assessments for one or both instruments, for at least one time point where the MAUI algorithm (either instrument) could generate the instrument's utility valuations or scores were included in the analyses (Table 2).

Baseline socio-demographic and clinical data were analysed descriptively as mean [standard deviation (SD)] for continuous variables and frequency (%) for categorical variables. BMI was calculated as weight (kg)/[height (m)]^2. Percentage total weight loss was calculated as weight loss (kg)/initial weight (kg) $\times$ 100, and percentage excess weight loss was calculated as total weight loss/{initial weight $-$ [25 $\times$ height (m)^2]} $\times$ 100. Height and weight data were collected from medical records at the study's three time points.

Utility valuations were generated for the EQ-5D-5L using the most recent UK value based on directly elicited preferences [33, 34] (range $-$0.281 to 1.00 utility points) and for the AQoL-8D using the most recent Australian scoring algorithm available on the AQoL group's website (http://www.aqol.com.au) (range +0.09 to 1.0 utility points). Summary statistics of both MAUIs' utility valuations and EQ-VAS were assessed as mean (SD) and median (IQR), and for individual and super dimension scores (AQoL-8D), they were assessed as mean (SD).

A minimal clinically important difference or minimal important difference is the smallest difference in score in the outcome of interest which patients perceive as beneficial and which would mandate a change in the patient's management [46, 47]. A recently reported composite minimal important difference for the EQ-5D-5L of selected chronic health conditions including hypertension, heart disease, arthritis, asthma or chronic obstructive pulmonary disease, cancer, diabetes, chronic back pain, and anxiety or depression has been calculated as 0.04 utility points [35]. We adopted this recent EQ-5D-5L composite measure for our study because of the array of complex physical and psychosocial health conditions included in the measure of minimal important difference. There is no reported minimal important difference for the AQoL-8D; however, there is a reported minimal important difference for the AQoL-4D. This is a composite measure that also includes chronic health conditions [37]. We therefore conservatively reported a minimal important difference for the AQoL-8D as the upper bound of the confidence interval (CI) of the AQoL-4D's minimal important difference (95% CI 0.03–0.08), namely, 0.08 points [37].

AQoL-8D Australian population norms for the total population and the 45- to 54-year-old age group were sourced from recently derived and published norms for the instrument [48].

Given that the MAUI-generated data are not normally distributed and also the relatively small sample size, this study employed the Wilcoxon signed rank test to test for statistical significance at the 5% level ($p \leq 0.05$). The Wilcoxon signed rank test for significance is the non-parametric counterpart of the paired t test, and corresponds to a test of whether the median of the differences between paired observations is zero in the population from which the sample is drawn [49].

We undertook sensitivity analyses on the subgroup of individuals who fully completed both MAUIs' questionnaires for all three reported time points (called 'full-completers') to test the robustness of all results including significance testing.

Statistical analyses were undertaken using IBM SPPS (version 22) or R (version 3.0.2).

3 Results

3.1 Participants' Clinical and Socio-demographic Characteristics and Questionnaire Completion

Twenty-three participants were recruited to the study and completed at least one of the MAUIs' questionnaires at one of the reportable time points to enable the generation of utility valuations (both instruments) and individual and super dimension scores (AQoL-8D only) (Table 2).

For these participants (n = 23), mean (SD) age was 50 (10) years, 43% were males, and mean (SD) time on the public waiting list for bariatric surgery was 6.5 (2.0) years. Table 2 (supported by Appendix) also provides results regarding changes in BMI, percentage total weight lost, and percentage excess weight lost. At 1 year postoperatively, the percentage of total weight lost was mean (SD) 16% (7.1%). BMI decreased from mean (SD) 49.3 (9.3) kg/m^2 before surgery to 43.5 (7.2) (3 months) to 40.8 (7.0)

(1 year) after surgery, giving rise to a significant reduction of 8.5 BMI units preoperatively to 1 year postoperatively ($p = 0.02$).

Appendix provides the socio-demographic characteristics of all participants ($n = 23$), the subgroup of full-completers of both questionnaires at all three reportable time points ($n = 9$), and the subgroup of participants who did not fully complete all questionnaires at the three reportable time points ($n = 14$). There was no substantial difference in age or sex [all participants ($n = 23$) males 43%; full-completers ($n = 9$) males 44%; partial-completers ($n = 14$) males 42%]. The order of magnitude for the number of years on the public waiting list was also similar. The postoperative obesity classifications and mean (SD) BMI measures were similar between the subgroups, and the magnitudes of change between obesity classifications were also similar between the subgroups.

Questionnaire completion for the entire cohort across the three reported time points is outlined in detail in Table 2. Overall, utility valuations could be assessed for 75% of participants for both MAUIs, and for individual and super dimension scores for the AQoL-8D only. Subgroup analyses were conducted for full-completers of both instruments' questionnaires across all three time points ($n = 9$) (outlined below and Tables 2 and 3).

3.2 Changes in Both Instruments' Utility Valuations Compared to BMI

Table 2 provides summary results for changes in BMI, utility valuations (both instruments), and EQ-VAS scores at the three reported time points. Figure 1 also provides a schematic representation of utility changes for the entire cohort ($n = 23$) and full-completers ($n = 9$). Figure 2 provides the distribution of utility valuations at the individual level for both instruments (Fig. 2a EQ-5D-5L and Fig. 2b AQoL-8D) 1 year after surgery.

Our study's key finding was that change in both instruments' summary utility valuations and also the EQ-VAS scores reported clinical improvements that exceeded the minimal important difference for all participants ($n = 23$) (EQ-5D-5L 0.08 utility points; AQoL-8D 0.16 utility points; EQ-VAS 16 points) from before surgery to 1 year after surgery. Importantly, the change in utility valuations derived for the AQoL-8D was twice that for the EQ-5D-5L (0.16 vs. 0.08 utility points) for the 1-year time horizon. Further, the AQoL-8D utility change from baseline to 1 year was statistically significant ($p = 0.04$), whereas only a trend was observed for the EQ-5D-5L ($p = 0.25$) (Table 2; Fig. 1). When we compared preoperative versus 1-year postoperative utility increases to BMI reductions over the same time horizon, we found that for every 1.0-unit reduction in BMI, the AQoL-8D utility valuation increased 0.02 units, compared with a 0.01 increase in utility for the EQ-5D-5L.

Another important finding was that from 3 months to 1 year postoperatively, the mean EQ-5D-5L utility valuation showed a slight decrease, by 0.02 utility points, whereas the mean AQoL-8D utility valuation gave rise to the third of the identified increases in utility for this instrument across the three time points (+0.06 utility points). An increase was also observed in the EQ-VAS scores from 3 months to 1 year. Notwithstanding these general trends, all changes from the reported 3 months to 1 year time point were not statistically significant (Table 2).

After surgery utility valuations at the individual level for both instruments were not normally distributed and the AQoL-8D revealed a wider dispersion (Fig. 2).

Subgroup analyses revealed that the orders of magnitudes, general trends, and significance testing of all our findings were robust when only the full-completers ($n = 9$) were analysed (Tables 2, 3). For example, from before surgery to 1 year after surgery, we found that the AQoL-8D's improvement in utility score 1 year after surgery was 0.15 points and the BMI reduction was 8.0 BMI units as compared with 0.16 utility points and a BMI reduction of 8.5 BMI units for the entire cohort (Tables 2, 3).

3.3 Assessment of Individual Domains of HRQoL: AQoL-8D Individual and Super Dimension Scores

Table 3 provides a comparison of the AQoL-8D's individual dimensions (Independent Living, Senses, Pain, Happiness, Coping, Self-worth, Relationships, and Mental Health) and Physical and Psychosocial super dimensions for the three reported time points, and subgroup analyses and significance testing for the full-completers subgroup from before surgery to 1 year after surgery.

A key finding for our particular study population of long-term waitlisted patients a year after bariatric surgery was that all individual and super dimension scores within the AQoL-8D improved. The individual psychosocial dimensions of Happiness, Coping, and Self-worth improved the most over this time horizon (0.12, 0.12, and 0.10 point improvements, respectively). The individual physical dimensions of Independent Living and Pain also improved (0.10 and 0.11 points, respectively). Additionally, Happiness and Coping approached general population norms [48]. These results were robust to subgroup analysis of full-completers of all three questionnaires (Table 3). Importantly, significance testing of the full-completers' results revealed that Happiness ($p = 0.01$), Coping ($p = 0.01$), Self-worth ($p = 0.03$), and the Psychosocial super dimension ($p = 0.008$), and the summary AQoL-8D utility valuation ($p = 0.01$) were statistically significant (Table 3).

Appendix 4A: Publication of "An exploratory study of long-term waitlisted bariatric surgery patients' quality of life before and 1 year after bariatric surgery, and considerations for healthcare planners".

Table 2 Comparison of study participants' (total participants, $n = 23$) BMI, summary health state utility valuations for the EQ-5D-5L and the AQoL-8D, and EQ-VAS scores before and 3 months and 1 year after bariatric surgery, and sensitivity analyses for full completers ($n = 9$)

	Before surgery	3 months after surgery	1 year after surgery	Change in mean from 3 months to 1 year after surgery and ToS** ($p \leq 0.05$)	Change in mean from before surgery to 1 year after surgery and ToS** ($p \leq 0.05$)
Years on public waiting list, mean (SD)	6.5 (2.0)†				
BMI (kg/m^2)	($n = 21$)	($n = 21$)	($n = 22$)	−2.7 BMI points, $p = 0.40$	−8.5 BMI points, $p = 0.02$**
Mean (SD)	49.3 (9.3)*	43.5 (7.2)	40.8 (7.0)		
%TWL, mean (SD)	NA	NA	16% (7.1)	NA	16%
%EWL, mean (SD)	NA	NA	34% (14.9)	NA	34%
MAUIs' HSUVs and EQ-VAS scores ($n = x$)					
EQ-5D-5L	($n = 16$)	($n = 19$)	($n = 18$)		
Mean (SD)	0.70 (0.25)	0.80 (0.25)	0.78 (0.25)	−0.02 utility points, $p = 0.92$	+0.08 utility points, $p = 0.25$
Median (IQR)	0.73 (0.54–0.91)	0.84 (0.59–0.86)	0.86 (0.67–0.93)		
AQoL-8D	($n = 15$)	($n = 18$)	($n = 17$)		
Mean (SD)	0.51 (0.24)	0.61 (0.24)	0.67 (0.23)	+0.06 utility points, $p = 0.66$	+0.16 utility points, $p = 0.04$**
Median (IQR)	0.51 (0.29–0.78)	0.58 (0.43–0.78)	0.67 (0.48–0.86)		
EQ-VAS	($n = 16$)	($n = 19$)	($n = 18$)		
Mean (SD)	57 (25)	67 (24)	73 (19)	+6 points, $p = 0.31$	+16 VAS score, $p = 0.08$
Median (IQR)	65 (34–73)	65 (48–90)	80 (56–90)		
Subgroup analysis*	($n = 9$)				
BMI (kg/m^2), mean (SD)	47.6 (7.4)	43.6 (6.1)	39.6 (6.4)	4.0 BMI points	−8.0 BMI points
%TWL, mean (SD)	NA	NA	16.6% (7.3)	NA	16.6%
%EWL, mean (SD)	NA	NA	36.3% (15.8)	NA	36.3%
EQ-5D-5L utility, mean (SD)	0.69 (0.21)	0.80 (0.15)	0.73 (0.20)	−0.07 utility points, $p = 0.52$	+0.04 utility points, $p = 0.26$
AQoL-8D utility, mean (SD)	0.45 (0.19)	0.57 (0.21)	0.60 (0.22)	+0.03 utility points, $p = 0.07$	+0.15 utility points, $p = 0.01$**
EQ-VAS, mean (SD)	59 (22)	66 (22)	67 (21)	+1 VAS score	+ 8 VAS score, $p = 0.18$

BMI body mass index, *EWL* excess weight lost, *HSUV* health state utility valuation, *IQR* interquartile range, *MAUI* multi-attribute utility instrument, *NA* not applicable, *SD* standard deviation, *ToS* test of significance, *TWL* total weight lost, *VAS* visual analogue scale

† One long-term waitlisted patient's time on the waiting list not available

* Full-completers subgroup analysis before and 3 months and 1 year after bariatric surgery

** ToS Wilcoxon rank test ($p \leq 0.05$)

4 Discussion

Our exploratory study is the first study to investigate the HRQoL impacts using both the EQ-5D-5L and AQoL-8D for a study population of severely obese, long-term publicly waitlisted patients who were then able to access bariatric surgery in 2015 because of a 2014 State Government public policy decision to reduce waiting times and to surgically treat long-waiting patients.

We found that the participants' responses to the EQ-5D-5L and AQoL-8D generated clinical improvements in utility valuations and EQ-VAS scores from before surgery to 1 year after surgery, where the minimal important differences were exceeded. Another important finding was

Table 3 Comparison of AQoL-8D individual and super dimension scores before and 3 months and 1 year after surgery (total participants, $n = 23$), Australian population norms, and subgroup (sensitivity) analysis

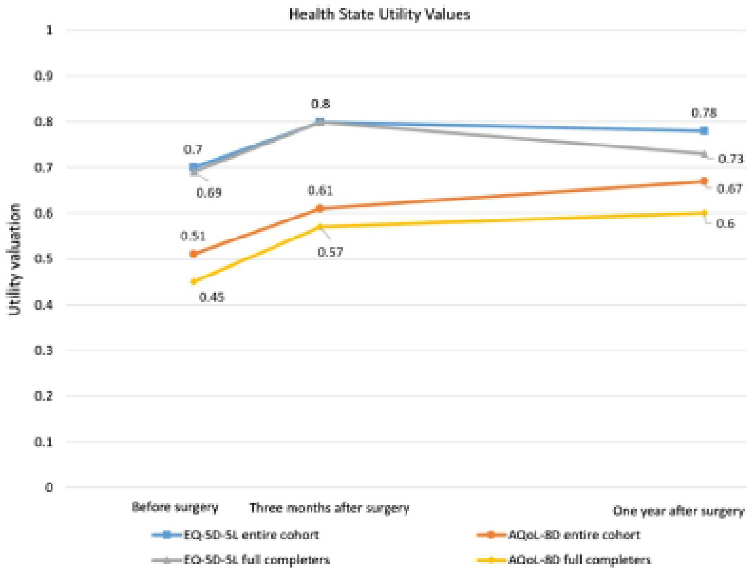
	Before surgery ($n = 15$), mean (SD)	3 months after surgery ($n = 18$), mean (SD)	1 year after surgery ($n = 17$), mean (SD)	Improvement in mean score preoperatively to 3 months and 1 year postoperatively (change)	Australian population norms		Subgroup (sensitivity) analysis ($n = 9$)		
					45- to 54-year-old age group, mean (SD)	Total, mean (SD)	Before surgery, mean (SD)	1 year after surgery, mean (SD)	Test of significance* ($p \leq 0.05$)
AQoL-8D individual and super dimensions									
Individual dimensions of physical health									
Independent Living	0.69 (0.22)	0.75 (0.19)	0.79 (0.20)	+0.06; 0.10	0.93 (0.12)	0.94 (0.11)	0.65 (0.20)	0.73 (0.21)	$p = 0.14$
Senses	0.81 (0.13)	0.83 (0.13)	0.84 (0.11)	+0.02; 0.03	0.88 (0.10)	0.91 (0.10)	0.81 (0.14)	0.86 (0.12)	$p = 0.29$
Pain	0.56 (0.34)	0.62 (0.32)	0.67 (0.31)	+0.06; 0.11	0.84 (0.21)	0.86 (0.19)	0.51 (0.31)	0.61 (0.30)	$p = 0.22$
Individual dimensions of psychosocial health									
Happiness	0.65 (0.16)	0.75 (0.15)	0.77 (0.13)	+0.10; 0.12	0.77 (0.16)	0.80 (0.15)	0.61 (0.16)	0.76 (0.11)	$p = 0.01$**
Coping	0.67 (0.15)	0.76 (0.15)	0.79 (0.12)	+0.09; 0.12	0.80 (0.16)	0.83 (0.15)	0.62 (0.10)	0.78 (0.09)	$p = 0.01$**
Relationships	0.62 (0.16)	0.67 (0.18)	0.71 (0.18)	+0.05; 0.09	0.78 (0.16)	0.79 (0.16)	0.59 (0.17)	0.66 (0.16)	$p = 0.08$
Self-worth	0.65 (0.21)	0.76 (0.18)	0.75 (0.19)	+0.11; 0.10	0.84 (0.16)	0.85 (0.15)	0.73 (0.19)	0.73 (0.18)	$p = 0.03$**
Mental Health	0.54 (0.12)	0.60 (0.15)	0.62 (0.19)	+0.06; 0.08	0.67 (0.17)	0.69 (0.17)	0.53 (0.09)	0.59 (0.18)	$p = 0.25$
Super dimensions									
Physical super dimension	0.51 (0.29)	0.56 (0.27)	0.62 (0.26)	+0.05; 0.11	0.79 (0.20)	0.83 (0.18)	0.46 (0.27)	0.55 (0.24)	$p = 0.13$
Psychosocial super dimension	0.25 (0.15)	0.37 (0.25)	0.41 (0.25)	+0.12; 0.16	0.47 (0.24)	0.50 (0.24)	0.20 (0.11)	0.34 (0.23)	$p = 0.008$**
HSUV	0.51 (0.24)	0.61 (0.24)	0.67 (0.23)	+0.10; 0.16	0.77 (0.20)	0.80 (0.19)	0.45 (0.19)	0.60 (0.22)	$p = 0.01$**

HSUV health state utility valuation, *SD* standard deviation

* Wilcoxon signed rank test significant at $p \leq 0.05$

** Significant result at ($p < 0.05$)

Fig. 1 Comparison of the EQ-5D-5L and AQoL-8D health state utility valuations before surgery and 3 months and 1 year after surgery



that the AQoL-8D's increase in utility valuation (0.16 utility points) was twice that of the EQ-5D-5L increase (0.08 utility points) at 1 year, with the AQoL-8D result statistically significant (and robust to subgroup analyses of the full-completers).

4.1 Public Resource Allocation to Bariatric Surgery: Waiting Lists and Patient Prioritisation

Our key findings highlighted two important and inextricably linked points regarding the assessment and utilisation of utility valuations for long-term waitlisted patients who subsequently undergo bariatric surgery. First, choice of an appropriate MAUI to preferentially capture and assess HRQoL for this study population is crucial. Second, sub-optimal public resource allocation decisions regarding the 'optimal' amount of bariatric surgery will likely occur if utility valuations, as an input measure of health impact for health economic evaluation (specifically cost-utility analyses), are generated by an instrument that is not sensitive to this study population's complex HRQoL.

Health economic evaluation is an important resource allocation methodology because it provides decision-makers with comparable analyses to underpin decisions about committing scarce healthcare resources to one use instead of another [14]. Cost-utility analyses of bariatric surgery to date have been dominated by use of the EQ-5D MAUIs [14]. Economic evaluation of interventions which affect HRQoL commonly employ cost-utility analyses which prioritise interventions according to the cost per quality-adjusted life-year. The estimation of quality-adjusted life-years is increasingly based upon the utility valuations predicted from an MAUI [50]. One of our study's key findings was that the AQoL-8D's utility changes/impacts from before surgery to 1 year after surgery were twice the magnitude of the EQ-5D-5L. Additionally, the EQ-5D-5L reported a plateauing utility valuation from 3 months to 1 year, in contrast to the AQoL-8D, which revealed a clinical improvement. If the nominated instrument lacks sensitivity within a particular health context (or health domain), interventions (such as bariatric surgery) affecting health states where the chosen instrument's sensitivity is low, will likely be disadvantaged [24, 50].

A recent study that investigated EQ-5D-5L utility valuations for patients who had undergone surgery at a Canadian Bariatric Centre for Excellence ($n = 304$ before surgery, $n = 138$ after surgery, 45% completion rate after surgery) found that mean utility valuation before and 1 year after surgery was 0.65 (before)/0.90 (after) utility points (for 'other' bariatric surgery) and 0.70 (before)/0.90 (after) utility points (for Roux-en-Y bariatric surgery) [51]. These results are similar to the order of magnitude of our exploratory study's EQ-5D-5L preoperative results. We note that the higher postoperative valuation for the Canadian study could be explained by the low completion rate, arguably of patients who would rate themselves closer to perfect health (45% of patients only responding 1 year postoperatively), and the EQ-5D-5L's inability to detect health impacts closer to perfect health (ceiling effects).

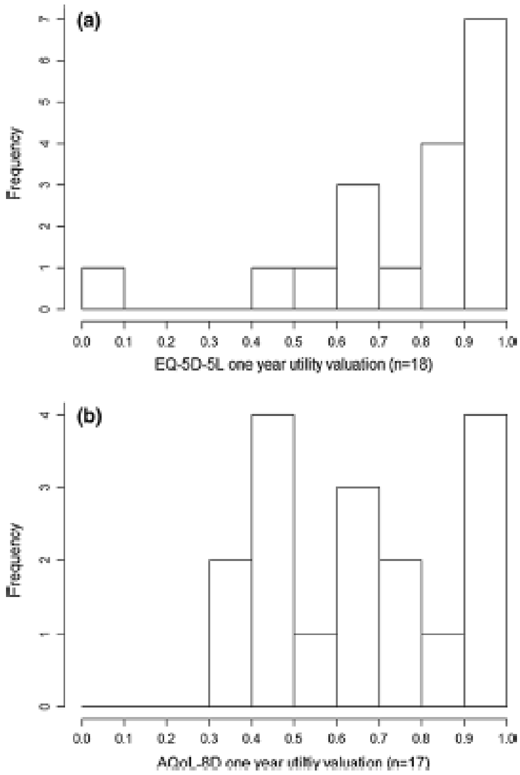


Fig. 2 Frequency distributions of utility valuations at the individual level for the EQ-5D-5L ($n = 18$) (**a**) and AQoL-8D ($n = 17$) (**b**) for the entire cohort 1 year after bariatric surgery

In contrast, our study's AQoL-8D preoperative summary utility valuations of mean (SD) 0.51 (0.24) indicated a significantly diminished HRQoL for our study population before surgery that was also reflected in the AQoL-8D's individual and super dimension scores. In turn, the AQoL-8D's ability to preferentially capture HRQoL (compared with the EQ-5D-5L) for our study population of long-term waitlisted patients who then subsequently underwent bariatric surgery is reflected in the reduced utility valuations. One of the key findings of our earlier research that conducted a head-to-head comparison of the two instruments was that the EQ-5D-5L and AQoL-8D are not interchangeable for people who had undergone bariatric surgery many years previously [24]. This study of long-term waitlisted patients also suggests that the AQoL-8D preferentially captures HRQoL and that the two instruments are not interchangeable for long-term waitlisted patients who subsequently undergo bariatric surgery.

Recent evidence has found that utility valuations measured by the major MAUIs differ [namely, the EQ-5D-5L, SF-6D, Health Utilities Index (HUI) 3, 15D and AQoL-8D] [50]. Most of these differences can be explained by the descriptive/classification systems of the MAUIs. These 'dominating' differences are estimated to explain an average of 66% of the difference between utilities obtained by the MAUIs (i.e. EQ-5D-5L, SF-6D, HUI 3, 15D, and AQoL-8D) and 81% of the difference between the utilities of the EQ-5D-5L and AQoL-8D [50]. In turn, our study's findings reflect the relative sensitivities of the EQ-5D-5L's and AQoL-8D's classification systems to our study population's physical and psychosocial domains of health. The AQoL-8D's changes in utility valuation were predominantly driven by the AQoL-8D's individual psychosocial dimensions and Psychosocial super dimension scores.

The AQoL-8D's utility valuations differed significantly from before surgery to 1 year after surgery, predominantly driven by the AQoL-8D's individual psychosocial and Psychosocial super dimension scores. Cost-utility analyses of the health impacts for long-term waitlisted patients who subsequently undergo bariatric surgery should appropriately reflect these health impacts. Our findings are particularly important because cost-utility analyses of bariatric surgery are dominated by the EQ-5D MAUIs [14].

In summary, long-term publicly waitlisted patients are an important and emerging subgroup of bariatric surgery patients, yet there is a paucity of evidence regarding longitudinal HRQoL impacts for this population if they are successful in getting publicly funded bariatric surgery. Our findings show that previously long-waiting patients with substantially diminished HRQoL did show significant improvements in HRQoL after surgery. This is important in that it shows clearly that long-waiting patients should not be 'written off'—they can still realise significant improvements in HRQoL outcome when ultimately treated. A recent cost-utility study from Sweden, the first study to quantify the potential impact of extensive waiting times on the costs and clinical outcomes of bariatric surgery, highlighted the necessity of reducing waiting lists and removing unnecessary barriers to allow greater utilisation of surgery for patients unresponsive to conservative medical management [10]. Nevertheless, addressing this issue, given the large gap between the demand for and supply of publicly funded bariatric surgery, which has resulted in protracted wait times for the procedure in countries such as Australia, Canada, and the UK [17, 52] and the longest of any surgical procedure in Canada (average 5 years) [17], would require significant commitment and investment.

4.2 Weight Status is Only One Factor Contributing to Complex HRQoL for Long-Term Waitlisted Patients Who Undergo Bariatric Surgery

Another important finding of our study is that the AQoL-8D's individual and super dimension scores identify psychosocial health as an important driver of holistic postoperative health 1 year after bariatric surgery. The AQoL-8D's Psychosocial super dimension almost doubled in magnitude from before surgery to 1 year after surgery, and this change was statistically significant. This result is validated by a recent systematic review of the literature regarding the quality-of-life outcomes of bariatric surgery, where the SF-36 was the most commonly used HRQoL instrument and the quality-of-life subscale for mental health showed improvements in three of the six included SF-36 studies [25]. Notably, none of these studies generated utility valuations or scores. Our study's AQoL-8D Psychosocial super dimension result is also validated by recent literature which suggests that psychosocial health status increases up to 4 years after bariatric surgery, but declines after this timeframe [22, 23].

Utility valuations have also been found to be independent predictors of health impacts [44]. Our study's results also support our earlier findings that if the choice of MAUI appropriately captures the individual and study population's physical and psychosocial health status through the sensitivity of the MAUI's dimensions/classification system, then the MAUI's predictive qualities could be a useful clinical measurement tool to rapidly and conveniently assess the intervention's likely health impacts in individuals and for the study population [24].

Our study also found that relative to BMI unit reductions, the AQoL-8D recorded 0.02-utility point increases for 1.0-BMI unit reductions, and for the EQ-5D-5L, 0.01-utility point increases for 1.0-BMI unit reductions. A recent study found that for the EQ-5D-3L, for a 1.0-unit BMI reduction there was a 0.0051–0.0075 increase in utility. Notwithstanding the differing classification systems and utility valuations of the two MAUIs, the AQoL-8D recorded a greater utility increase per unit of BMI reduction. We contend that this difference was driven by the impact of psychosocial health—the AQoL-8D's broader (depth and breadth) psychosocial classification system captured and assessed domains of health that are not 'weight change' or 'BMI change' related. Our findings are also supported by a recent cross-sectional study that compared quality of life measured by the Moorehead–Ardelt Quality of Life Questionnaire in obese patients 12–18 months after bariatric surgery that found there is a limited relationship between BMI and HRQoL [42].

In summary, we contend that the importance of psychosocial factors in driving the measured improvements in HRQoL should not be lost on policy-makers in allocating resources. Much recent debate on bariatric surgery has focused on the physical health impacts of weight loss, especially on its potential to avoid or mitigate the worst effects of diabetes. However, if much of the real health gain observed derives from psychosocial impacts, this may have important consequences for patient selection and prioritisation decisions.

4.3 Increased Mobility

We also found that the AQoL-8D's individual physical dimensions of Independent Living and Pain improved from before surgery to 1 year after surgery. A recent study that conducted proportional analysis for the EQ-5D-5L has found that mobility significantly increases 1 year after bariatric surgery [51]. The increases in the AQoL-8D individual physical dimensions of health and the Physical super dimension further support these findings.

Only 10 of the 35 items of the AQoL-8D capture and assess the physical domains of health that inform the individual physical dimensions of Independent Living, Senses, and Pain. A recent study suggests that the AQoL-8D's descriptive system is preferential to psychosocial health rather than physical health [53].

4.4 Supporting Qualitative Evidence

Some of our study's participants participated in long interviews for an associated qualitative study regarding the support needs of patients waiting for publicly funded bariatric surgery [18]. The findings of this study indicated that waiting for bariatric surgery was commonly associated with a range of deleterious consequences including weight gain and deteriorating physical and psychosocial health [18]. These qualitative findings both support and provide further contextualisation and nuance to our study's baseline AQoL-8D utility valuations and individual and Psychosocial and Physical super dimension scores that revealed substantially reduced summary utility valuations and scores that were well below the relative Australian population norms (Table 3). Our study has shown that our cohort's HRQoL was substantially diminished before surgery, and this qualitative evidence also suggests it is likely that utility valuations and individual and super dimension scores could have been measurably lower for our unique cohort if long-waiting patients were left untreated.

4.5 Limitations

There are a number of limitations to our study. The first limitation is sample size. Nevertheless, our study was exploratory and we were provided with a novel opportunity to recruit participants from the long-term waitlisted patients subsequently fast-tracked for bariatric surgery through a government policy decision to reduce waiting lists. The second limitation is that all participants were operated on by the same surgeon in the same hospital. This could affect the generalisability of our results if scaled up to all bariatric surgery patients. The third limitation is that there is no control arm in the study. The observational nature of our study did not enable the recruitment of a control arm to elicit utility valuations. The fourth limitation is the use of the UK value set for the EQ-5D-5L because there is no Australian value set available for the instrument. The final limitation is that the sample is at risk of participant selection bias, which could also affect the generalisability of our results. Recent evidence has found that public sector waiting times are years in duration in some countries and that there are physical (worsening of comorbidities and further weight gain) and psychosocial impacts for patients waiting for bariatric surgery.

A strength of our study is the high response rate of 75% to the questionnaires across all three reportable time points. Additionally, our study is an exploratory study of long-term waitlisted patients and could inform larger confirmatory studies of HRQoL (particularly assessed through utilities derived from generic MAUIs) for long-term waitlisted patients who subsequently undergo bariatric surgery.

5 Conclusions

Our exploratory study of long-term waitlisted patients recruited opportunistically following a government policy decision to reduce waiting lists suggests that long-waiting bariatric surgery patients should not be 'written off' by healthcare planners; they can still realise significant improvements in HRQoL outcomes when ultimately treated, and this should be factored into patient prioritisation decisions. Addressing this issue given the large gap between the demand for and supply of publicly funded bariatric surgery in many countries would require significant commitment and investment.

Ongoing improvements in psychosocial parameters from 3 months to a year post-surgery explained improvements in overall utility valuation measured by the AQoL-8D that were not detected by EQ-5D-5L. Selection of a sensitive instrument is crucial to adequately measure changes in utility valuation and to accurately reflect changes in quality-adjusted life-years generated for cost-utility analyses. Cost-utility analyses for long-term waitlisted patients for bariatric surgery should employ utility valuations from MAUIs that are sensitive to physical and psychosocial health changes. Only through comprehensive assessments of HRQoL impacts before and after surgery can we robustly inform public resource allocation decisions. We found that the AQoL-8D preferentially captures these health impacts compared with the EQ-5D-5L.

Coupled with BMI assessment, pre-surgery utility valuations should be investigated as independent predictors of post-surgery HRQoL (particularly psychosocial health status) for morbidly obese, long-term waitlisted, bariatric surgery patients.

Authorship Julie Campbell contributed to study design, data verification and analysis, and manuscript preparation and final approval. Martin Hensher contributed to study design and manuscript review and final approval. Amanda Neil contributed to study design and manuscript review and final approval. Alison Venn contributed to study design and manuscript review and final approval. Stephen Wilkinson contributed to study design and manuscript review and final approval. Andrew Palmer contributed to study design, data verification and analysis, and manuscript preparation and final approval.

Compliance with Ethical Standards

Ethical standards The University of Tasmania's Health and Medical Human Research Ethics Committee (HMHREC) approved this study, and informed consent was obtained from all participants in accordance with the HMHREC's guidelines. This study was performed in accordance with the ethical standards of the Declaration of Helsinki.

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Conflicts of interest The authors Julie Campbell, Martin Hensher, Amanda Neil, Alison Venn, Stephen Wilkinson, and Andrew Palmer declare they have no conflict of interest.

Informed consent Informed consent was obtained from all individual participants included in the study.

Data Availability Statement The dataset used for this study contains the following: the participant-reported responses to the EQ-5D-5L and the AQoL-8D MAUIs' questionnaires; the individual utility valuations (both instruments) and utility scores (AQoL-8D only) that were generated with the instruments' specific algorithm; the participant-reported EQ-VAS scores; and participants' socio-demographic and clinical data. The corresponding author will provide a de-identified dataset upon reasonable request for all or part of the data.

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Appendix

Participants' clinical and socio-demographic characteristics before and 1 year after surgery for the total fast-track cohort, the subgroup of participants who fully completed

Appendix 4A: Publication of "An exploratory study of long-term waitlisted bariatric surgery patients' quality of life before and 1 year after bariatric surgery, and considerations for healthcare planners".

both MAUIs at all three time points, and the subgroup of participants who were not full-completers ($n = 14$)

Characteristics	Fast-track cohort ($n = 23$)	Full-completers ($n = 9$)	Partial completers ($n = 14$)
Age years, mean (SD)	50 (10)	48 (11)	52 (9)
Sex ($n = x$, %)	Male (10, 43%)	Male (4, 44%)	Male (6, 42%)
	Female (13, 57%)	Female (5, 56%)	Female (8, 58%)
Number of years on public waiting list, mean (SD)	6.5 (2.0)**	7.3 (2.5)	6.1 (1.6)
Number of participants in obesity category ($n = x$, %)			
Before surgery			
BMI ≥ 30–34.9 kg/m^2 (Class I)	(1, 4%)	0	(1, 7%)
BMI ≥ 35–39.9 kg/m^2 (Class II)	0	0	0
BMI ≥ 40–49.9 kg/m^2 (Class III)	(13, 57%)	(7, 78%)	(6, 43%)
BMI ≥ 50 kg/m^2 *	(9, 39%)	(2, 11%)	(7, 50%)
12 months after surgery			
BMI ≥30–34.9 kg/m^2 (Class I)	(2, 10%)	(2, 14%)	(3, 21%)†
BMI ≥35–39.9 kg/m^2 (Class II)	(7, 33%)	(3, 21%)	(2, 14%)
BMI ≥40–49.9 kg/m^2 (Class III)	(9, 43%)	(3, 21%)	(6, 43%)
BMI ≥50 kg/m^2	(3, 14%)	(1, 11%)	(2, 14%)
BMI (kg/m^2)			
Before surgery, mean (SD)	49.3 (9.35)	47.6 (7.4)	49.9 (10.6)
After surgery, mean (SD)	40.8 (7.0)	39.6 (6.4)	41.6 (7.5)†
% Total weight lost, mean (SD)	16 (7.1)	NA	NA

MAUI multi-attribute utility instrument, *SD* standard deviation, *NA* not applicable

* Super-obese [54]

** One long-term waitlisted patient's time on the waiting list not available

† One missing value

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Chapter 5: An exploratory study: A head-to-head comparison of the EQ-5D-5L and AQoL-8D for long-term publicly waitlisted bariatric surgery patients before and 3 months after bariatric surgery.

Preface

This chapter is the second of two longitudinal studies (Chapters 4 and 5) that were based on a unique cohort of long-term waitlisted patients (mean years on the waiting list 6.5 (standard deviation) 2.0 years) who were then provided with bariatric surgery due to a public policy decision to reduce waiting lists.

Chapter 2 found that the EQ-5D is the most commonly used multi-attribute utility instrument in cost-utility analyses of bariatric surgery, however, the classification system of the EQ-5D focuses on physical health. In parallel with the previously published study (Chapter 4) that investigated the one year health impacts in long-term waitlisted patients, this current study also aimed to consolidate the findings of Chapter 3. Chapter 5 extends method of Chapter 3 by investigating *all* 13 dimensions (rather than 6 dimensions) of the two multi-attribute utility instruments supported by a longitudinal study design with a different cohort of bariatric surgery patients.

In support of the findings from the previously published head-to-head comparison in Chapter 3, Chapter 5 particularly highlights the depth and breadth of the AQoL-8D's classification system as compared to the EQ-5D-5L. These findings support the superior discriminant sensitivity of the AQoL-8D across the individual dimensions of physical and psychosocial health.

Dimensional comparisons found the individual dimensions that revealed the most similar distribution for both instruments were Pain/Discomfort (EQ-5D-5L) and Pain (AQoL-8D). Nevertheless, the AQoL-8D provided evidence of change in other domains of health that could be affected by pain, such as sleep, which impacts the Mental Health dimension.

This study also established clinically significant changes in psychosocial health even 3 months after surgery. Chapter 5 also revelaled that people who languish for long periods on the public waiting list can endure the same substantially diminished health-related quality of life as someone with metastatic cancer or prolonged heart disease.

The studies that comprise Chapters 4 and 5 of this thesis also investigated the emerging literature regarding the predictive capabilities of multi-attribute utility instruments in patient-centred bariatric care. Prediction is more likely to be accurate when the instrument used for prediction takes account of the full range of the complex physical and psychosocial problems associated with the problem. This study’s findings suggest that the AQoL-8D is more likely to provide correct prediction than the EQ-5D-5L.

This study provided much needed policy advice to the NHMRC project partner regarding the health gains that can still be realised when long-waiting bariatric surgery patients are ultimately treated, even there months after surgery. The study also provides the health economics community with further evidence (consolidating Chapter 3) that the AQoL-8D preferentially captures and assesses physical and psychosocial health-related quality of life for the broader bariatric surgery study population.

Chapter 5 has been published in *PharmacoEconomics – Open* (Appendix 5A). A fee waiver was granted for this publication.

Impact factor: *PharmacoEconomics – Open* is a new journal, nevertheless, the impact factor of *PharmacoEconomics* (the companion journal) is 3.63.

Campbell JA, Hensher M, Neil A, Venn A, Otahal P, Wilkinson S, and Palmer AJ. An exploratory study: a head-to-head comparison of the EQ-5D-5L and AQoL-8D for long-term publicly waitlisted bariatric surgery patients before and 3 months after bariatric surgery. *PharmacoEconomics – Open. 2017*. DOI: 10.1007/s41669-017-0060-1

Abstract

Background: Choice of a multi-attribute utility instrument (MAUI) that appropriately assesses an intervention's health-related quality-of-life (HRQoL) impacts is a vital part of healthcare resource allocation and clinical assessment.

Objectives: Our exploratory study compared the EuroQo (EQ)-5D-5L and Assessment of Quality of Life (AQoL)-8D MAUIs, which were used to assess the effect of bariatric surgery for a convenience cohort of long-term publicly waitlisted, severely obese patients.

Methods: The study was conducted at the Hobart Private Hospital (Tasmania, Australia). To compare the sensitivity and instrument content of the two MAUIs, we used dimensional comparisons by investigating the distribution of patient-reported responses (number/percentage) across the MAUIs' levels and dimensions; summary health-state utility valuations (utilities); and individual/super-dimension scores (AQoL-8D) to investigate discriminatory power and HRQoL improvements preoperatively and 3 months postoperatively

Results: Participants' (n = 23) overall MAUI completion rate was 74%. Postoperative total weight loss was 9.9%. EQ-5D-5L utilities were relatively higher pre- and post-operatively than AQoL-8D utilities [mean standard deviation (SD) EQ-5D-5L 0.70 (0.25) to 0.80 (0.25); AQoL-8D 0.51 (0.24) to 0.61 (0.24)]. AQoL-8D Psychosocial super dimension was relatively low postoperatively [0.37 (0.25)], driving the instrument's lower utility. These results were supported by the dimensional comparisons that revealed an overall greater dispersion for the AQoL-8D. Nevertheless, there were clinical improvements in utilities for both instruments. AQoL-8D utilities were lower than population norms; not so the EQ-5D-5L utilities. The AQoL-8D dimensions of Happiness, Coping, and Self-worth improved the most.

Conclusions: AQoL-8D more fully captured the impact of obesity and bariatric surgery on HRQoL (particularly psychosocial impacts) for long-term waitlisted bariatric surgery patients, even 3 months postoperatively. AQoL-8D preoperative utility revealed our population's HRQoL was lower than people with cancer or heart disease.

Key points for decision makers
The Assessment of Quality of Life (AQoL)-8D may have superior discriminatory sensitivity compared to the EuroQol (EQ)-5D-5L for long-term waitlisted severely obese bariatric surgery patients.
There is potential for sub-optimal healthcare resource allocation if the selected multi-attribute utility instrument does not appropriately assess health-related quality-of-life (HRQoL) impacts for the bariatric surgery study population
As an important and increasingly prevalent study population of bariatric surgery patients who inherently carry complex physical and psychosocial HRQoL needs, long-term waitlisted severely obese bariatric surgery patients showed improvements in HRQoL even 3 months postoperatively

5.1 Introduction

Demand for publicly funded bariatric care in many countries is high; however, capacity is limited by healthcare funding decisions. Consequently, bariatric (metabolic, obesity or weight-loss) surgery waiting lists are long [1, 2]. Prolonged delays generally exist for people waitlisted for primary bariatric surgery in public health systems in many countries, including Australia [3–5].

Whilst it is acknowledged that these protracted multi-year wait times are detrimental to the bariatric surgery candidate's physical and psychosocial health [2, 6, 7], recent evidence has established that weight status is just one factor contributing to the complex health-related quality-of-life (HRQoL) needs of people who have received bariatric surgery [8, 9]. Nevertheless, there is a paucity of quantitative evidence regarding HRQoL impacts for long-term waitlisted bariatric surgery patients who have experienced multiyear wait times on public waiting lists and then undergo bariatric surgery [10, 11].

Multi-attribute utility instruments (MAUIs) are a HRQoL assessment tool designed to rapidly and conveniently, assess and capture an individual's health-state utility values through application of pre-established formulae/weights to the array of responses obtained on the MAUI's questionnaire [9]. A MAUI is developed and defined with particular characteristics, including the number of questionnaire items; the depth and breadth of the descriptive/classification system; the number of health states described; the number of individual and super dimensions (if there are super dimensions); and the algorithmic range.

For example, the number of health states described for the EuroQol (EQ)-5D-3L and 5L, Health Utilities Index (HUI) 3, 15D, Short-Form 6 Dimension (SF-6D), Quality of Well-Being (QWB) and Assessment of Quality of Life (AQoL)-8D MAUIs range from 243; 3125; 972,000; 3.1 x 10^{10}; 18,000; 945; and 2.4 x 10^{23}, respectively [12]. Additionally, many MAUIs target physical health within their descriptive/classification systems. For example, for the EQ-5D-5L, one of its five dimensions relates to psychosocial health (Anxiety/Depression) and four out of five relate to physical health (Mobility, Self-care, Usual Activities and Pain) [13]. In contrast, for the AQoL-8D, three of the instrument's eight dimensions relate to physical health (Independent Living, Senses and Pain), and five of the eight dimensions relate to psychosocial health (Coping, Relationships, Self-worth, Happiness and Mental Health), and 25 of the 35 items (questions) inform the AQoL-8D's five psychosocial dimensions [14, 15]. The SF-6D describes six dimensions, namely Physical Functioning, Role Limitations, Social Functioning, Pain, Mental Health and Vitality [12, 16]. Both the AQoL-8D and SF-6D describe composite physical and psychosocial dimensions, namely the Physical and Psychosocial super dimensions (AQoL-8D), and the Physical and Mental Component Summaries (SF-6D) [14, 17].

A small number of MAUIs dominate the economic evaluation literature. These include the EQ-5D-3L (pre-cursor to the EQ-5D-5L), HUI 3 and SF-6D. A review of 1,663 studies between 2005 and 2010 found that these three instruments accounted for 63%, 9.9%, and 8.8% of the total, respectively [12]. Four other instruments in the review, the 15D, HUI 2, AQoL, and QWB, were used in 7%, 4.6%, 4.2%, and 2.5% of the studies, respectively [18].

A recent cross-sectional study of patients who had received bariatric surgery in the private healthcare system many years previously [median [interquartile range (IQR)] 5 (3-8) years] found that the AQoL-8D and EQ-5D-5L instruments were not interchangeable for the study population [9]. Another recent study that investigated the 1-year health impacts for long-term waitlisted bariatric surgery patients (and complementary to this study using the same cohort of patients), suggested that the AQoL-8D preferentially captured HRQoL for the study population

1 year after surgery [11]. Importantly, this 1-year study did not directly compare the distributions of patient-reported responses across the depth and breadth of the MAUIs' dimensions of health (dimensional comparisons) [11]. As a single MAUI instrument, the AQoL-8D captures the vast majority of domains considered crucial for people who are considering, or who have undergone, bariatric surgery [9].

The choice of MAUI should be influenced by the sensitivity of the instrument to a patient group's health profile [9, 12]. If the choice of instrument does not appropriately capture and assess the individual's and study population's health profiles (particularly for complex physical and psychosocial HRQoL), vital healthcare information about a clinical intervention's health impact will be omitted from important resource allocation and planning decisions [9].

Utility valuations are key health economic metrics that are an input measure in the assessment of quality-adjusted life years (QALYs) [19]. Utility valuations measure the strength of preference for a particular health state and are represented as a number on a scale where 1.0 represents the best possible health state and 0.0 represents death. In principle, values less than zero are possible when a health state is worse than death [20]. Utility values assessed by MAUIs are not equivalent, with the difference between the descriptive/classification systems of the MAUIs the principal determinant [12]. Additionally, differences in descriptive/classification systems are estimated to explain an average of 66% of the difference between utilities obtained by MAUIs, and 81% of the difference between the utilities of the EQ-5D-5L and AQoL-8D [12].

MAUIs were not initially developed for clinical use; however, utility valuations can also be used to inform and/or predict clinical outcomes [21]. Clinicians have found that measuring utilities is of benefit to patient–clinical assessment, relationships, communication, and management [22]. Many MAUIs (including the EQ-5D-5L and 3L, AQoL-4D, SF-6D, 15D and HUI) report minimal clinically important differences or minimal important differences for their utility valuations [23–28]. A minimal clinically important difference is the smallest difference in score in the outcome of interest that patients perceive as beneficial and which would mandate a clinical change in the patient's management (both individually and collectively for a particular study population) [22, 23, 29, 30].

There is a paucity of evidence regarding short-term HRQoL impacts for people who have received bariatric surgery [31, 32]. A study published in 2007 provided 3-month (range 3–6 months) HRQoL impacts of bariatric surgery using the SF-36 [33]. A second study published in 2001 provided 1-, 3- and 6-month HRQoL impacts of bariatric surgery using the SF-36, bariatric analysis and reporting outcome system (BAROS) and Moorhead-Ardelt quality-of-life questionnaires [34]. Both studies found short-term improvements in the quality of life scores (however, these studies did not generate, nor investigate, utility valuations) after bariatric surgery.

Whilst it is acknowledged that integrating patient-reported outcomes (PROs) in clinical practice has the potential to enhance patient-centred care [35], PROs are not yet routinely collected in bariatric care. A recent systematic review that identified and investigated prospective bariatric surgery studies that used validated PRO measures found that for PRO data to influence practice, well-designed and reported studies are required [36]. In turn, there is a potential for MAUIs to address this key gap regarding PROs in bariatric care subject to the particular MAUI's capacity to capture, assess and describe the relevant health states of the study population.

The main objective of this exploratory study was to directly compare the discriminatory power of two different MAUIs, namely the EQ-5D-5L and the AQoL-8D, which were used to assess the effect of bariatric surgery using a cohort of long-term publicly waitlisted, severely obese patients who underwent bariatric surgery as part of a government policy initiative to reduce waiting lists. As a secondary objective, we also aimed to investigate the role of the two MAUIs in the analysis of individual patient health states.

The EQ-5D suite of instruments dominates the clinical and economic literature, including that for bariatric surgery [14, 18]. Nevertheless, the AQoL-8D has been shown to have preferential psychometric properties compared to comparative MAUIs in study populations where the assessment of psychosocial health status is crucial, for example, intensive care unit (ICU) admissions (compared with SF-6D) [22] and people who had undergone bariatric surgery (compared with the EQ-5D-5L) [9, 11]. Additionally, a recent study that presented results from one of the broadest comparative surveys in terms of the range of diseases (arthritis, asthma, cancer, depression, diabetes, hearing loss and heart disease) and six MAUIs (EQ-5D-5L, SF-6D, HUI 3, 15D, QWB and AQoL-8D), and countries (Australia, the USA, the UK, Canada, Norway, and Germany) found that the AQoL-8D is the most sensitive instrument for measuring mental health [37]. This study also found that the pain component of the EQ-5D-5L has a greater impact than it does in any other instrument, and that the EQ-5D-5L is the most sensitive instrument for measuring pain [37]

Our exploratory study also investigated the relative magnitudes of the global utility valuations [12], clinical improvements of the utility valuations for both instruments, and also the impacts on individual domains of health through the AQoL-8D's individual and super-dimension scores.

In parallel with our previously published study that investigated the 1-year health impacts in long-term waitlisted patients [11], this current study aimed to investigate the distribution of the patient-reported responses of the two MAUIs for this population of public healthcare long-waiting bariatric surgery patients who inherently carry complex physical and psychosocial HRQoL needs.

5.2 Methods

5.2.1 Study design

(i) Recruitment of participants

Recruitment of our study participants is described in detail in our previously published study [11]. In summary, a Tasmanian government policy decision was made in 2014 to allocate additional and targeted public funds to provide morbidly obese, long-term waitlisted patients with bariatric surgery in 2015 [38]. All participants underwent laparoscopic adjustable gastric band (LAGB) surgery by the same surgeon in the Hobart Private Hospital. Laparoscopic banding was carried out using Apollo APS or APL bands, with adjustment ports attached to the left anterior rectus sheath [39]. Postoperative fluid diets were maintained for 3 weeks, with subsequent transition to normal foods, accompanied by instruction on eating technique and exercise.

All data were de-identified. Ethics approval was granted by the University of Tasmania's Health and Medical Human Research Ethics Committee (HMHREC) before our study's recruitment of participants.

(ii) The multi-attribute utility instruments and questionnaire completion

The selection and attributes of the EQ-D-5L and AQoL-8D MAUIs used in this study have previously been described in detail [11]. Another earlier study comparing the EQ-5D-5L and the AQoL-8D MAUIs for people who had undergone LAGB surgery many years previously provided a detailed summary of the divergent characteristics of the two purposively selected MAUIs [9, 11]. In summary, the two markedly different MAUIs were selected on the following basis: the EQ-5D-5L is the internationally prevalent instrument in economic evaluation (including the economic evaluation of bariatric surgery) [40]; four of the five instrument's health domains/classifications (and items) focus on physical HRQoL; and it takes less than 1 min to complete the EQ-5D-5L's questionnaire [13]. The EQ-5D-5L also contains a visual analogue scale (EQ-VAS) [22]. In contrast, the AQoL-8D's classification system is supported by psychometric principles and testing, and 25 of the instrument's 35 items capture and assess five (from eight) psychosocial domains of health, and three physical domains of health. The AQoL-8D describes billions of health states and takes 5 min to complete [14, 15, 41].

Participants were asked to self-complete both instruments' questionnaires before their bariatric surgery at the pre-admission preoperative clinics and at 3 months postoperatively. Postoperative questionnaires were mailed out for self-completion with an explanatory cover letter and reply-paid envelope enclosed. We evaluated EQ-5D-5L and AQoL-8D questionnaire completion by assessing the overall proportion of participants who completed the questionnaire(s) at the study's two time points for whom an individual utility value could be generated.

5.2.2 Data analysis

Participants with patient-reported HRQoL assessments for one or both instruments, for at least one time point where the MAUI algorithm (either instrument) could generate the instrument's utility valuations or scores were included in the analyses.

Descriptive baseline socio-demographic, clinical data, utility valuations and dimensional scores were presented as mean [standard deviation (SD)] and/or median (IQR) for continuous variables and frequency (%) for categorical variables. Body mass index (BMI) was calculated as weight (kg)/[height (m^2)] and classified as obese (BMI 30–34.9 kg/m^2), severely obese (BMI 35–39.9 kg/m2), morbidly obese (BMI 40–49.9 kg/m^2), and super obese (BMI ≥50 kg/m^2) [42].

(i) Discriminant sensitivity: dimensional comparisons (both instruments) and dimensional scores (AQoL-8D).

The relative discriminatory power of the instruments was investigated using two methodologies.

First, we calculated the distribution of participant responses across the levels and dimensions (the depth and breadth) of both instruments. This was achieved by collating the participant-reported response for each item and then calculating the percentage distribution of responses for each dimension [9, 16]. To illustrate, for the EQ-5D-5L individual dimension of Anxiety/Depression, the numbers of participants who gave each response level (1, 2, 3, 4 or 5) were converted to a percentage of the total number of participants in order to derive a 'five-level frequency distribution'. Detailed calculations for each item and dimension are provided in Appendix 1 [see the electronic supplementary material (ESM)]. Additionally, schematic representations of the dimensional comparisons were expressed as a percentage by calculating the average percentage before and after surgery. For example, the schematic representation of the physical dimensions of both instruments compared the average score of Mobility, Self-care, Usual Activities and Pain for the EQ-5D-5L and Independent Living, Sense and Pain for the AQoL-8D for each level before and after surgery.

Second, impacts on the individual domains of physical and psychosocial HRQoL were investigated through the AQoL-8D's summary scores for the eight individual dimensions and two super dimensions. The EQ-5D-5L generates a single utility valuation for an individual; however, it does not generate individual or summary scores for each and every one of its five separate dimensions.

(ii) Analyses of summary utility valuations and EQ-VAS scores

Utility valuations were generated for the EQ-5D-5L using the most recent UK value based on directly elicited preferences, the valuation ranging from - 0.281 to 1.0 utility points [43, 44]. All five questions require a valid response to generate a utility score. EQ-5D population norms are sourced from UK data because there are no available Australian population norms [45]. For the AQoL-8D, we used the current version of the scoring algorithm incorporating Australian weights published on the AQoL group's website (http://www.aqol.com.au) (valuation range +0.09 to 1.0 utility points). For the AQoL-8D's scoring algorithm, an overall utility valuation can be generated with ten missing values scattered over all dimensions. Australian population norms were sourced from recently published valuations [41]. Individual and super-dimensional scores are also generated with the AQol-8D's scoring algorithm.

A minimal clinically important difference (or minimal important difference) is the smallest difference in score in the outcome of interest which patients perceive as beneficial and which would mandate a change in the patient' management [23, 29, 30]. A recently reported composite minimal important difference for the EQ-5D-5L for chronic health conditions was reported as 0.04 utility points [46]. There is no established minimal important difference for the AQoL-8D; however, a minimal important difference for the AQoL-4D has previously been reported as 0.06 utility points, with a 95% confidence interval of 0.03–0.08 utility points [24]. This study conservatively adopted the upper bound of 0.08 utility points as the proxy minimal important difference for comparison of the pre- and post-operative AQoL-8D utility valuations. The established minimal important difference for the EQ-VAS is 10 points [47]. It has been suggested that with the expanded use of HRQoL endpoints (for example, analyses of utility valuations and scores within vastly different MAUI classification systems), the interpretation of HRQoL in the context of minimal important differences is imperative [23]. In turn, our study has included the interpretation of minimal important differences in its comparison of the EQ-5D-5L and AQoL-8D MAUIs.

Statistical analyses were undertaken using IBM SPPS (version 22) or R (version 3.0.2).

5.3 Results

5.3.1 Participants' characteristics and questionnaire completion

Twenty-three participants were recruited to the study. For these participants, mean (SD) age was 50 (10) years, 43% were males, and mean (SD) and median (IQR) time on the public waiting list for bariatric surgery was 6.5 (2.0) and 6.3 (5.0–7.8) years, respectively.

Table 1 provides pre- and postoperative results for BMI, percentage total weight lost and percentage excess weight lost. Before surgery 39% of participants were classified as super obese (BMI ≥50 kg/m^2) and 57% were classified as morbidly obese (BMI 40–49.9 kg/m^2). After surgery, there was a 26% reduction in the super-obesity category. Similarly, after surgery, the morbidly obese category was reduced by 17%.

In regard to questionnaire completion, there was a 74% completion rate of questionnaires overall [Tables 2, 3 and 4; Appendix 1 (see the ESM)].

Table 1: Number of participants (n=23) in obesity categories before and after surgery.

	Before surgery	After surgery*	Change
BMI			
Mean (SD)	49.3 (9.4)	43.5 (7.2)	- 5.8
Median (IQR)	45.5 (41.6 – 55.4)	43.2 (38.7 – 49.6)	- 2.3
BMI (n = x; %)			
BMI ≥ 30 34.9 kg/m² (Class I)	(1, 4%)	(2, 9%)	(+ 1, + 6%)
BMI ≥ 35 39.9 kg/m² (Class II)	0	(7, 30%)	(+ 7, + 33%)
BMI ≥ 40 - 49.9 kg/m² (Class III)	(13, 57%)	(9, 39%)	(- 4, - 17%)
BMI ≥ 50 kg/m² **	(9, 39%)	(3, 13%)	(- 6, - 26%)
Weight (kg)			
Mean (SD)	139.7 (31.4)	125.9 (26.9)	- 13.8
Median (IQR)	134.0 (118.8 – 161.5)	124.5 (106.9 – 142.2)	- 8.1
% Total weight lost			
Mean (SD)	NA	9.9 (6.2)	NA
Median (IQR)	NA	11.0 (3.7 – 15.0)	NA
% Excess weight lost			
Mean (SD)	NA	21.5 (13.1)	NA
Median (IQR)	NA	24.7 (12.6 – 28.2)	NA

BMI, body mass index; IQR, interquartile range; SD standard deviation
N = 21*: 2 participants 3 month weight not available
** super obese (≥50kg/m²)

5.3.2 Sensitivity: dimensional comparisons

The relative discriminatory power of the instruments was investigated using the dimensional comparisons outlined in section 2.2.1.

Table 2 (supported by Appendix 1 in the ESM) presents the 'before' and 'after' surgery distribution of participant responses for both MAUIs' 13 individual dimensions/domains of health across levels 1–5 (EQ-5D-5L) and levels 1 to 4–6 (AQoL-8D). Figure 1a–c also provide a schematic representation of the comparative distribution of the participants' responses across levels 1–6 for all dimensions (Figure 1a), and for the physical dimensions of health for both instruments (EQ 5D-5L: Mobility, Self-care, Usual Activities and Pain; AQoL-8D: Independent Living, Senses and Pain) (Figure 1b), and the psychosocial dimensions of health for both instruments (EQ-5D-5L: Anxiety/Depression; AQoL-8D: Coping, Mental Health, Relationships, Self-worth, Happiness) (Figure 1c).

None of the participants responded to level 6 for the AQoL-8D items that provided for a level 6 response [namely Independent Living (one item), Senses (two items: vision and hearing), Mental Health (one item) and Relationships (one item)] (Table 2 and Appendix 1). Table 2 and Figure 1a–c (supported by Appendix 1) revealed a more even dispersion of participant responses for the AQoL-8D than the EQ-5D-5L both pre- and postoperatively. The AQoL-8D more clearly distinguished between health states that are close to full health for the study population (Table 2, Figure 1a–c, Appendix 1).

More specifically, postoperatively participants recorded 80% (76/95) of responses for the EQ-5D-5L at level 1 (perfect health: I have no problems) and level 2 (I have slight problems), the highest recorded response at level 1 being 74% for Self-care (decreased from 81% before surgery) (Table 2; Appendix 1). These results highlight the EQ-5D-5L's inability to distinguish between health states close to full/perfect health (utility score 1.0). Additionally, for the EQ-5D-5L's only psychosocial dimension of health (Anxiety/Depression), participants did not record responses at level 4 (I am severely anxious or depressed), nor level 5 (I am extremely anxious or depressed), indicating that the EQ-5D-5L's only psychosocial dimension is relatively limited. Before surgery, only 6% of participants recorded both levels 4 and 5 for Anxiety/Depression (Table 2, Appendix 1, and Figure 1c). Participants recorded responses at level 4 (16%) for one of the EQ-5D-5L's individual dimensions (Pain) after surgery (Table 2; Appendix 1).

In contrast, participants' postoperative responses to the AQoL-8D questionnaire were less concentrated in the upper levels (i.e. more evenly dispersed across the levels), with only 58%

(365/630) of responses recorded at levels 1 and 2 (Table 2, Figure 1a, and Appendix 1), the highest level being 41% for Senses.

Participants also recorded responses at level 4 for all the AQoL-8D’s individual dimensions, and participants also recorded responses at level 5 for both Pain and Mental Health. Additionally, the lowest percentage of participants scored at level 1 for the AQoL-8D’s individual dimensions of Happiness (15%), Coping (19%) and Mental Health (26%) (Table 2; Appendix 1). Nevertheless, Happiness and Coping substantially improved and approached population norms (Table 3), and this result is also revealed with the improvement of participants’ preoperative scores at level 1 in Happiness (from 3% to 15%) and Coping (from 11 to 19%) (Table 2; Appendix 1).

The individual dimension that had the most similar distribution for both instruments across levels 1–5 was Pain/Discomfort for the EQ-5D-5L (level 1: 26%, level 2: 32%, level 3: 26%, level 4: 16% and level 5: 0%) and Pain for the AQoL-8D (level 1: 35%, level 2: 19%, level 3: 31%, level 4: 13%and level 5: 2%) (Table 2; Appendix 1). Three of the 35 AQoL-8D items contribute to the dimension of Pain. These items capture and assess how often the respondent suffers for the first Pain item ‘serious pain’, for the second Pain item the severity of ‘pain or discomfort’, and for the third Pain item of how often pain interferes with usual activities. The EQ-5D-5L individual dimension of Pain/Discomfort assesses the level of severity of pain/discomfort (no pain/discomfort, slight, moderate, severe, extreme).

5.3.3 Sensitivity: comparison of changes in utility valuations

Table 4 provides summary statistics for the changes in both instruments’ utility valuations preoperatively to 3 months postoperatively. The EQ-5D-5L revealed relatively higher summary utility valuations than the AQoL-8D both before and after surgery. Specifically, the order of magnitude of the EQ-5D-5L's mean utility valuations were 0.19 utility points greater than the mean AQoL-8D utility valuations preoperatively and 3 months postoperatively. The AQoL- 8D particularly showed low summary utility valuations before surgery [EQ-5D-5L 0.70 (0.25); AQoL-8D 0.51 (0.24)].

Three months after surgery, the summary utility valuations revealed clinical improvements for both instruments. Nonetheless, the AQoL-8D showed substantially lower postoperative summary utility valuations than the EQ-5D-5L. More specifically, the EQ-5D-5L utility value increased by 0.10 points from mean (SD) 0.70 (0.25) to 0.80 (0.25). Similarly, the AQoL-8D utility value increased by 0.10 points from 0.51 (0.24) to 0.61 (0.24) (Table 4). After surgery, the EQ-5D-5L utility valuations approached comparable population norms, but not so the AQoL-8D's utility valuations. The UK general population mean for the EQ-5D-5L is 0.86 [45], and for the AQoL-8D the general Australian population norm is 0.80 (0.19), and for the 45–54-year age group, it is 0.77 (0.20) [41] (Table 4).

Table 4 also provides mean (SD) pre- and postoperative EQ-VAS scores of 57 (25) to 67 (24) points, the difference equalling the established EQ-VAS minimal important difference of 10 points.

5.3.4 AQoL-8D individual/super-dimension scores

Table 3 provides the AQoL-8D's individual and super-dimension scores before surgery and 3 months after surgery, and the Australian population norms at the individual dimensional level for the general population and the 45–54-year age group. Additionally, Figure 2a, b provide a schematic representation of the individual and super-dimensional scores compared with the general Australian population norm. The EQ-5D-5L does not generate individual or super-dimension scores.

Improvements were observed for all eight individual dimension scores and the two super-dimension scores even 3 months after surgery. Three months after surgery, the Physical super dimension improved 0.05 points to mean (SD) 0.56 (0.27) points and the Psychosocial super-dimension score improved 0.12 points to 0.37 (0.25) points. Of the eight individual dimensional scores, Self-worth and Happiness improved the most 3 months after surgery by revealing gains of 0.11 points (Self-worth) and 0.10 points (Happiness). The postoperative scores for Happiness 0.75 (0.15) and Coping 0.76 (0.15) also approached both the 45–54-year age group and general population norms. Happiness was only 0.02 points less than the 45–54-year age group population norm and Coping was only 0.04 points less than the 45–54-year age group population norm.

Other individual dimensional scores that improved by 0.05 points after surgery were Coping (0.09 points), Mental Health (0.06 points) and Relationships (0.05 points), which contribute to the Psychosocial super dimension. With regard to the Physical super dimension, Independent Living and Pain both improved 0.06 points and Senses showed a smaller improvement of 0.02 points (Table 3).

As mentioned previously, the cohort’s HRQoL before surgery was substantially lower in comparison to population norms (Table 3; Figure 2a, b). Individual dimensional scores improved 3 months postoperatively, but did not substantially approach Australian population norms, with the exception of two dimensions: Happiness and Coping (Table 3; Figure 2a). The Psychosocial and Physical super dimensions’ scores, while improved, were still substantially lower than the Australian general population norm at- 0.13 and - 0.27 points, respectively. The Physical super-dimension score was driven by the Pain dimension scoring 0.24 points less than the general population norm. Independent Living and Relationships also revealed large differences, scoring -0.19 and - 0.13 points from the general population norm. Similarly, Mental Health/Self-worth and Senses also revealed scores of 0.09/0.09 and 0.08 less than their Australian general population norm equivalents, respectively. In contrast, the individual dimensions of Happiness and Coping approached both the general and 45–54-year age group population norms (Table 3; Figure 2a, b).

Table 2: Dimensional comparisons of response rates (%) for all individual dimensions of the EQ-5D-5L and AQoL-8D before surgery and 3 months after bariatric surgery.

	EQ-5D-5L				
	Mobility	Personal Care	Usual Activities	Pain/ Discomfort	Anxiety/ Depress-ion
Before surgery (n=16)					
Level 1	38%	81%	50%	31%	25%,
Level 2	25%	6%	13%,	13%	38%
Level 3	31%	13%	25%	25%	25%
Level 4	6%	0	13%	31%	6%
Level 5	0	0	0	0	6%
Level 6	NA	NA	NA	NA	NA
After Surgery (n=19) (%point change †)					
Level 1	53% (+ 15)	74% (-7)	53%(+3)	26% (-5)	47% (+22)
Level 2	26% (+1)	21% (+15)	32%(+19)	32% (+19)	37% (-1)
Level 3	21% (-10)	5% (- 8)	16% (- 9)	26% (+1)	16% (-9)
Level 4	0 (-6)	0 (0)	0 (0)	16% (-15)	0 (-6)
Level 5	0 (0)	0 (0)	0 (0)	0 (0)	0 (-6)
Level 6	NA	NA	NA	NA	NA

	AQoL-8D							
	Physical super dimension			**Psycho-social super dimension**				
	Independ-ent Living (4 items)	Pain (3items)	Senses (3items)	Coping (3 items)	Mental Health (8 items)	Happiness (4 items)	Relation-ships (7 items)	Self Worth (3 items)
Before surgery (n=15)								
Level 1	27 %	29 % *	31 %	11 %	19 %*	3 %	24 % *	18 %*
Level 2	17 %	20 %	40 %	36 %	23 %	33 %	31 %	20 %
Level 3	30 %	27 %	29 %	29 %	36 %	42 %	29 %	33 %
Level 4	18 %	18 %	0	20 %	15 %	17 %	9 %	24 %
Level 5	8 %	7 %	0	4 %	8 %	5 %	8 %	4 %
Level 6	0	NA	0	NA	0	NA	0	NA
After surgery (n=18)								
Level 1	26% (-1)	35% (+6)	*41% (+10)	19% (+8)	26%* (+7)	15% (+12)	33% (+9)	30% (+12)
Level 2	31% (+14)	19% (-1)	30% (-10)	44% (+8)	24% (+1)	38% (+5)	34% (+3)	26% (+6)
Level 3	29% (-1)	31% (+4)	26% (-3)	24% (-5)	44% (+8)	39% (-3)	23% (-6)	31% (-2)
Level 4	14% (-4)	13% (-5)	4% (+4)	13% (-7)	4%(-11)	8% (-9)	10% (+1)	13% (-11)
Level 5	0 (-8)	2% (-5)	0 (0)	0 (0)	1% (-7)	0 (-5)	0 (-8)	0 (-4)
Level 6	0 (0)	NA	0 (0)	NA	0 (0)	NA	0 (0)	NA

Detailed calculations supporting Table 2 are contained in Appendix 1
AQoL-8D items: AQoL-8D Independent Living: 4 aqol items: household tasks levels 1-5, getting around levels 1-6, mobility levels 1-6, self-care levels 1-5; AQoL-8D Pain: 3 aqol items: frequency of pain levels 1-4, degree of pain levels 1-4, pain interference levels 1-5; AQoL-8D Senses: 3 aqol items: vision levels 1-6, hearing levels 1-6, communication levels 1-4; AQoL-8D Coping: 3 aqol items: energy levels 1-5, being in control levels 1-5, coping with problems levels 1-5; AQoL-8D Mental Health: 8 aqol items: feelings of depression levels 1-6, trouble sleeping levels 1-5, feelings of anger levels 1-5, self-harm levels 1-5, feeling despair levels 1-5, worry levels 1-5, sadness levels 1-5, tranquillity/agitation levels 1-5; AQoL-8D Happiness: 4 aqol items: contentment levels 1-5, enthusiasm levels 1-5, degree of feeling happiness levels 1-5, pleasure levels 1-5; AQoL-8D Relationships:7 aqol items: relationship with family and friends levels 1-6 and levels 1-5, social isolation levels 1-5, social exclusion levels 1-5, intimate relationship levels 1-5, family role levels 1-5 community role levels 1-4; and AQoL-8D Self-worth:3 aqol items: feeling like a burden levels 1-5, worthlessness levels 1-5, confidence levels 1-5.
AQoL, Assessment of quality of life
* Columns add to 99 or 101% due to rounding
†Figure in brackets after surgery reflects the percentage point change (i.e. ‘after surgery’ minus ‘before surgery’)

Table 3: Comparison of the AqoL-8D individual and super-dimension scores before surgery and 3 months after surgery (total participants; n=23), and Australian population norms for total population and 45-54 year age group.

	Before bariatric surgery (n=15)			**After bariatric surgery** (n=18)			**Improvement in mean score preoperatively to three months postoperatively**	**Australian population norms**	
								(45–54 years)	Total
AQoL-8D individual and super-dimensions	**Mean (SD)**	**Min**	**Max**	**Mean (SD)**	**Min**	**Max**	**Change**	**Mean (SD)**	**Mean (SD)**
Dimensions of physical health									
Independent Living	0.69 (0.22)	0.39	1.00	0.75 (0.19)	0.41	1.00	+ 0.06	0.93 (0.12)	0.94 (0.11)
Senses	0.81 (0.13)	0.56	1.00	0.83 (0.13)	0.59	1.00	+ 0.02	0.88 (0.10)	0.91 (0.10)
Pain	0.56 (0.34)	0.16	1.00	0.62 (0.32)	0.21	1.00	+ 0.06	0.84 (0.21)	0.86 (0.19)
Dimensions of psychosocial health									
Happiness	0.65 (0.16)	0.32	0.85	0.75 (0.15)	0.51	1.00	+ 0.10	0.77 (0.16)	0.80 (0.15)
Coping	0.67 (0.15)	0.39	0.96	0.76 (0.15)	0.51	1.00	+ 0.09	0.80 (0.16)	0.83 (0.15)
Relationships	0.62 (0.16)	0.47	1.00	0.67 (0.18)	0.47	1.00	+ 0.05	0.78 (0.16)	0.79 (0.16)
Self-worth	0.65 (0.21)	0.35	1.00	0.76 (0.18)	0.39	1.00	+ 0.11	0.84 (0.16)	0.85 (0.15)
Mental Health	0.54 (0.12)	0.28	0.73	0.60 (0.15)	0.36	0.96	+ 0.06	0.67 (0.17)	0.69 (0.17)
Super-dimensions									
Physical super dimension	0.51 (0.29)	0.18	0.97	0.56 (0.27)	0.22	1.00	+ 0.05	0.79 (0.20)	0.83 (0.18)
Psycho-social super dimension	0.25 (0.15)	0.08	0.49	0.37 (0.25)	0.12	0.97	+ 0.12	0.47 (0.24)	0.50 (0.24)
Utility value for AQoL-8D	0.51 (0.24)	0.20	0.83	0.61 (0.24)	0.29	1.00	+ 0.10	0.77 (0.20)	0.80 (0.19)

Max, maximum; Min, minimum; SD, standard deviation.

Table 4: Summary statistics for EQ-5D-5L and AQoL-8D at baseline (before surgery), difference between the two measures at baseline, and changes in the participants' scores over 3 months of follow up (total participants; n = 23).

	EQ-5D-5L (baseline) (n=16)	EQ-5D-5L (after surgery) (n=19)	EQ-5D-5L change (after surgery - baseline)	AQoL-8D (baseline) (n=15)	AQoL-8D (after surgery) (n=18)	AQoL-8D change (after surgery - baseline)	Difference in baseline/after surgery scores: (EQ-5D-5L - AQoL-8D)	EQ-VAS (baseline) (n=16)	EQ-VAS (after surgery) (n=19)	EQ-VAS change (baseline to three months)
Mean	0.70	0.80	0.10	0.51	0.61	0.10	0.19 / 0.19	57	67	10
SD	0.25	0.25	0	0.24	0.24	0	0.01 / 0.10	25	24	(1)
Median	0.73	0.84	0.11	0.51	0.58	0.07	0.22 / 0.29	65	65	0
IQR	0.54 – 0.91	0.59 - 0.86	NA	0.29 – 0.78	0.43 – 0.78	NA	NA	34 – 73	48 – 90	NA
Minimum	0.24	0.46	0.22	0.20	0.29	0.09	0.04 / 0.17	15	27	12
Maximum	1.00	1.00	0	0.83	1.00	0.17	0.17 / 0	95	99	4

Appendix 1 – Electronic Supplementary Material: Detailed calculations of the dimensional comparisons of response rates for all individual dimensions of the EQ-5D-5L and AQoL-8D

EQ-5D-5L

	Mobility	**Personal Care**	**Usual Activities**	**Pain/ Discomfort**	**Anxiety/ Depression**
Before surgery					
(n=16)					
(% = X/16)					
Level 1	38 %, (6/16)	81 %,(13/16)	50 %, (8/16)	31 %, (5/16)	25 %, (4/16)
Level 2	25 %, (4/16)	6 %, (1/16)	13 %, (2/16)	13 %, (2/16)	38 %, (6/16)
Level 3	31 %, (5/16)	13 %, (2/16)	25 %, (4/16)	25 %, (4/16)	25 %, (4/16)
Level 4	6 %, (1/16)	0	13 % , (2/16)	31 %, (5/16)	6 %, (1/16)
Level 5	0	0	0	0	6 %, (1/16)
Level 6	NA	NA	NA	NA	NA
After surgery					
(n=19)					
(% = X/19)					
Level 1	53 %, (10/19)	74 % (14/19)	53 %, (10/19)	26 %, (5/19)	47 %, (9/19)
Level 2	26 %, (5/19)	21 % (4/19)	32 %, (6/19)	32 %, (6/19)	37 %, (7/19)
Level 3	21 %, (4/19)	5 %, (1/19)	16 % (3/19)	26 %, (5/19)	16 %, (3/19)
Level 4	0	0	0	16 %, (3/19)	0
Level 5	0	0	0	0	0
Level 6	NA	NA	NA	NA	NA

AQoL-8D

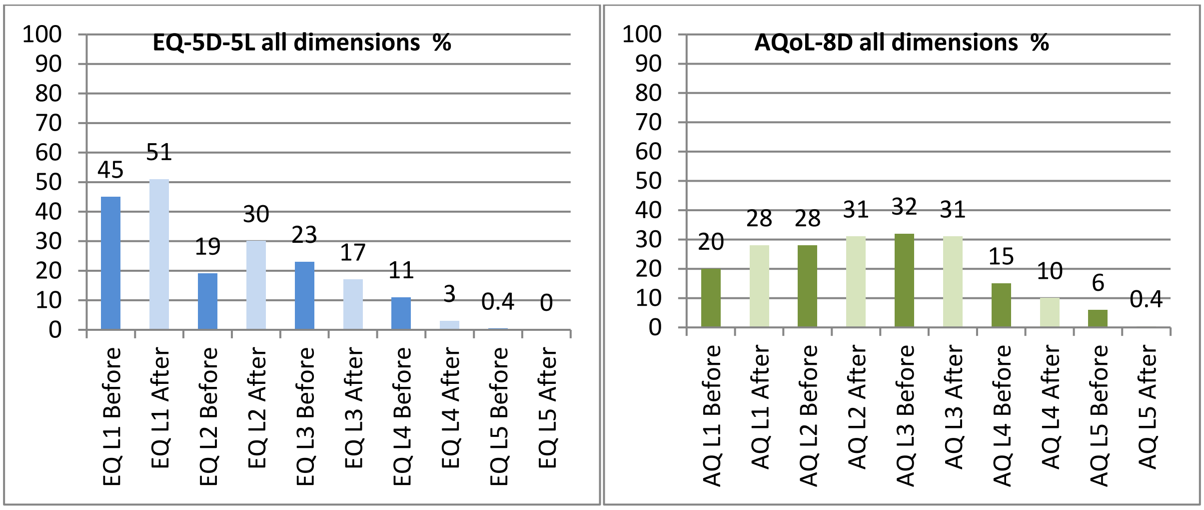
	Physical super dimension components			**Psychosocial superdimension components**				
	Independent Living (4 items)	**Pain (3 items)**	**Senses (3 items)**	**Coping (3 items)**	**Mental Health (8 items)**	**Happiness (4 items)**	**Relationships (7 items)**	**Self Worth (3 items)**
Before surgery								
(n=15)								
(% = X/[15*items])								
Level 1	27 %, (16/60)	29 %, (13/45)	31 %, (14/45)	11 %, (5/45)	19 %, (23/120)	3 %, (2/60)	24 %, (25/104)**	18 %, (8/45)
Level 2	17 %, (10/60)	20 %, (9/45)	40 %, (18/45)	36 %, (16/45)	23 %, (27/120)	33 %, (20/60)	31 %, (32/104)	20 %, (9/45)
Level 3	30 %, (18/60)	27 %, (12/45)	29 %, (13/45)	29 %, (13/45)	36 %, (43/120)	42 %, (25/60)	29 %, (31/104)	33 %, (15/45)
Level 4	18 %, (11/60)	18 %, (8/45)	0	20 %, (9/45)	15 %, (18/120)	17 %, (10/60)	9 %, (9/104)	24 %, (11/45)
Level 5	8 %, (5/60)	7 %, (3/45)	0	4 %, (2/45)	8 %, (9/120)	5 %, (3/60)	8 %, (7/104)	4 %, (2/45)
Level 6	0	NA	0	NA	0	NA	0	NA
After surgery								
(n=18)								
(% = X/[18*items])								
Level 1	26 %, (19/72)	35 %, (19/54)	41 %,(22/54)*	19 %, (10/54)	26 %, (38/144) *	15 %, (11/72)	33 %(41/125)**	30 %, (15/54)
Level 2	31 %, (22/72)	19 %, (10/54)	30 %, (16/54)	44 %, (24/54)	24 %, (35/144)	38 %, (27/72)	34 %, (43/125)	26 %, (13/54)
Level 3	29 %, (21/72)	31 %, (17/54)	26 %, (14/54)	24 %, (13/54)	44 %, (63/144)	39 %, (28/72)	23 %, (29/125)	31 %, (15/54)
Level 4	14 %, (10/72)	13 % (7/54)	4 %, (2/54)	13 %, (7/54)	4 %, (6/144)	8 %, (6/72)	10 %, (12/125)	13 %, (5/54)
Level 5	0	2 %, (1/54)	0	0	1 %, (2/144)	0	0	0
Level 6	0	NA	0	NA	0	NA	0	NA

Notes:

AQoL-8D Independent Living: 4 aqol items: household tasks levels 1-5, getting around levels 1-6, mobility levels 1-6, self-care levels 1-5;
AQoL-8D Pain: 3 aqol items: frequency of pain levels 1-4, degree of pain levels 1-4, pain interference levels 1-5;
AQoL-8D Senses: 3 aqol items: vision levels 1-6, hearing levels 1-6, communication levels 1-4;
AQoL-8D Coping: 3 aqol items: energy levels 1-5, being in control levels 1-5, coping with problems levels 1-5;
AQoL-8D Mental Health: 8 aqol items: feelings of depression levels 1-6, trouble sleeping levels 1-5, feelings of anger levels 1-5, self-harm levels 1-5, feeling despair levels 1-5, worry levels 1-5, sadness levels 1-5, tranquillity/agitation levels 1-5;
AQoL-8D Happiness: 4 aqol items: contentment levels 1-5, enthusiasm levels 1-5, degree of feeling happiness levels 1-5, pleasure levels 1-5;
AQoL-8D Relationships:7 aqol items: relationship with family and friends levels 1-6 and levels 1-5, social isolation levels 1-5, social exclusion levels 1-5, intimate relationship levels 1-5, family role levels 1-5 community role levels 1-4
AQoL-8D Self-worth:3 aqol items: feeling like a burden levels 1-5, worthlessness levels 1-5, confidence levels 1-5.
* percentage adds to 101 or 99 due to rounding
** 1 missing response: algorithm allows 2 missing responses to generate health state utility values

Figure 1: (a) Distribution of participants' responses (%) for levels (L) 1–5 for all dimensions of EQ-5D-5L and AQoL-8D before surgery and 3 months after surgery; (b) Distribution of participants' responses (%) for Levels (L) 1–5 for the combined physical dimensions of EQ-5D-5L (Usual Activities, Self-care, Mobility, Pain) and AQoL-8D (Independent Living, Senses, Pain) before surgery and 3 months after surgery. c Distribution of participants' responses (%) for Levels (L) 1–5 for the combined psychosocial dimensions of EQ-5D-5L (Anxiety/Depression) and AQoL-8D (Coping, Mental Health, Happiness, Relationships, Self-worth) before surgery and 3 months after surgery.

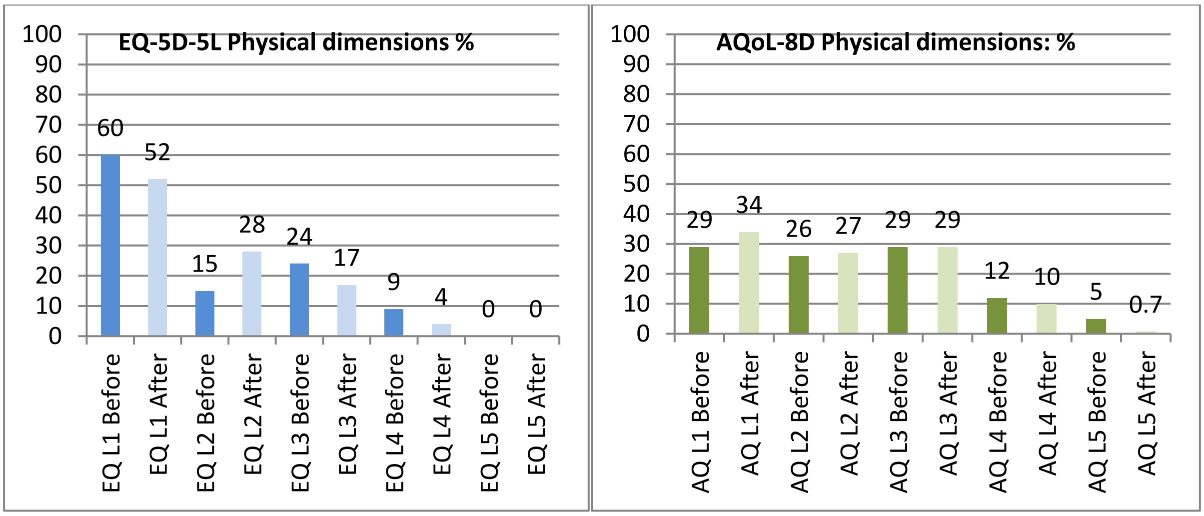
Figure 1a



EQ-5D-5L five individual dimensions: Usual Activities, Self-care, Mobility, Pain and Anxiety/Depression.

AQoL-8D eight individual dimensions: Independent Living, Senses, Pain, Happiness, Coping, Relationships, Self-worth,

Figure 1b

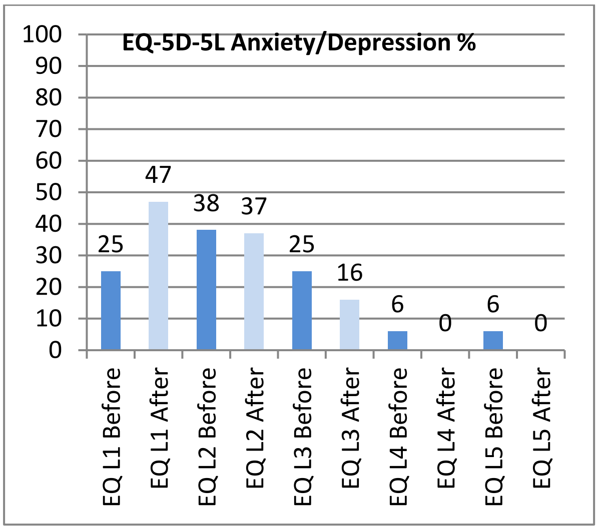


EQ-5D-5L four physical dimensions: Usual Activities, Self-care, Mobility and Pain.

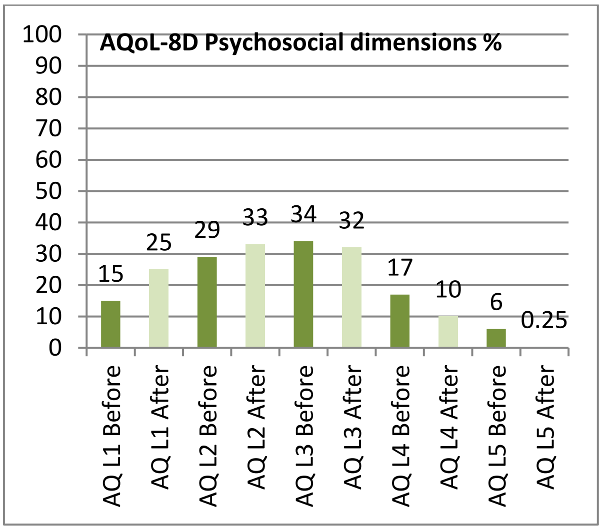
AQoL-8D three physical dimensions: Independent Living, Senses and Pain.

Figure 1: (a) Distribution of participants' responses (%) for levels (L) 1–5 for all dimensions of EQ-5D-5L and AQoL-8D before surgery and 3 months after surgery; (b) Distribution of participants' responses (%) for Levels (L) 1–5 for the combined physical dimensions of EQ-5D-5L (Usual Activities, Self-care, Mobility, Pain) and AQoL-8D (Independent Living, Senses, Pain) before surgery and 3 months after surgery. c Distribution of participants' responses (%) for Levels (L) 1–5 for the combined psychosocial dimensions of EQ-5D-5L (Anxiety/Depression) and AQoL-8D (Coping, Mental Health, Happiness, Relationships, Self-worth) before surgery and 3 months after surgery.

Figure 1c



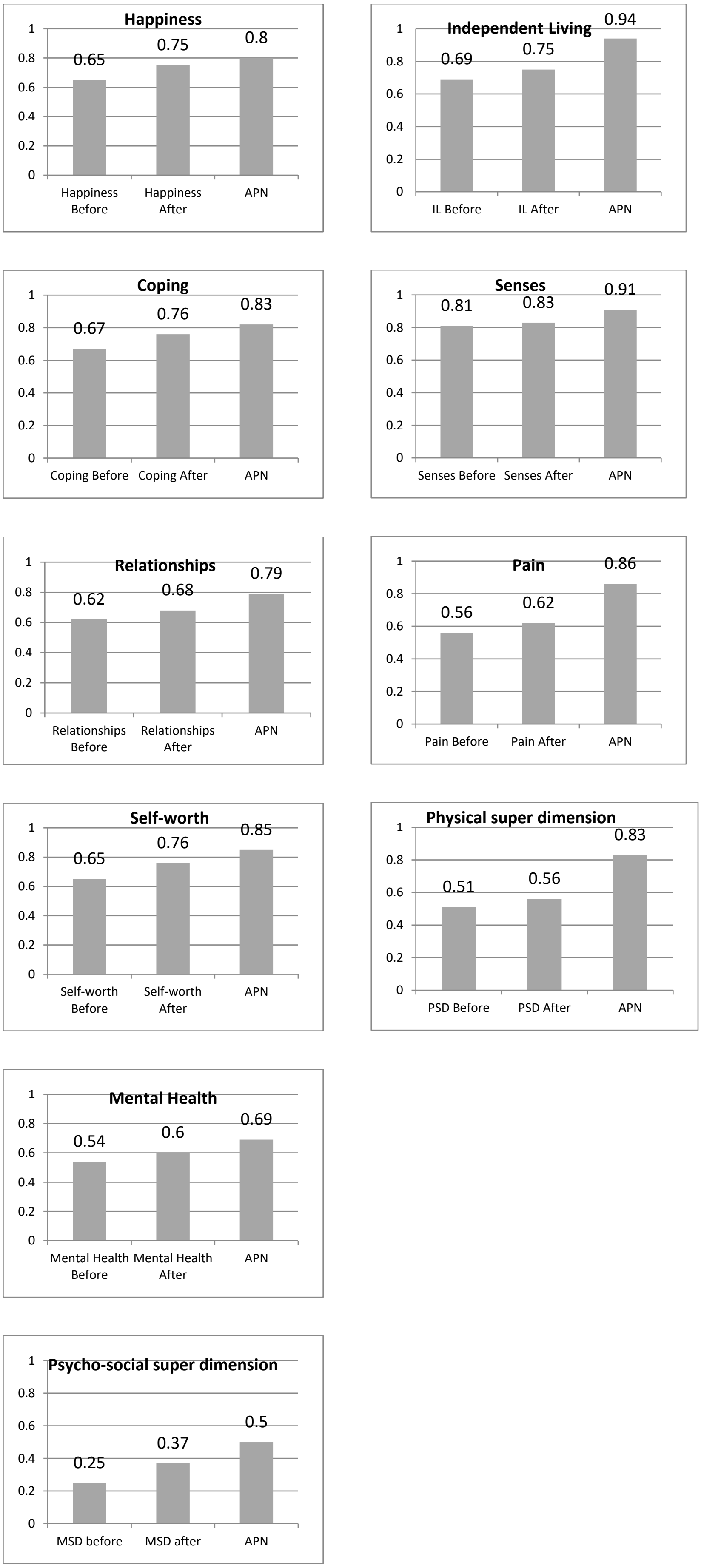
EQ-5D-5L one psychosocial dimension: Anxiety/depression



AQoL-8D five psychosocial dimensions Happiness, Coping, Relationships, Self-worth, Mental Health

Figure 2: (a) Comparison of before surgery and 3 months after bariatric surgery AQoL-8D scores and Australian Population norms (APN) for the individual psychosocial dimensions (Happiness, Coping, Relationships, Self-worth, Mental Health) and the Psychosocial super dimension.

(b) Comparison of before surgery and 3 months after bariatric surgery AQoL-8D scores and Australian Population norms (APN) for the individual physical dimensions (Independent Living, Senses, Pain) and the Physical super Dimension.



5.4 Discussion

Our study is important because it is the first study to investigate the relative discriminatory power using dimensional comparisons of all 13 individual dimensions of the EQ-5D-5L and AQoL-8D for patients who endured multiyear wait times in a public health system and then underwent bariatric surgery.

As an important and emerging subgroup of bariatric surgery patients, our cohort also delivered an important and novel opportunity to provide clinicians with a better understanding of the 3-month postoperative impact of bariatric surgery on long-term waitlisted patients' complex physical and psychosocial domains of health.

5.4.1 A head-to-head comparison of the EQ-5D-5L and AQoL-8D revisited

In support of our findings from our previously published cross-sectional head-to-head comparison of privately treated patients who received bariatric surgery many years previously [9], this current longitudinal study revealed that the AQoL-8D preferentially captured and assessed the physical and psychosocial HRQoL for our cohort of long-term waitlisted patients who subsequently underwent bariatric surgery, even 3 months after their surgery.

Amongst other direct comparisons of the discriminatory power of the two instruments, our earlier head-to-head study's comparison of the patient-reported distribution of the levels of response compared three (total six) individual comparable dimensions of both instruments (EQ-5D-5L: Anxiety/Depression, Self-care, Pain/Discomfort; AQoL-8D: Mental Health, Independent Living, Pain) [9]. In contrast, this current paper's head-to-head comparison conducted a longitudinal investigation for a study population of long-term publicly waitlisted bariatric surgery patients who underwent bariatric surgery as a targeted government policy decision to reduce waiting lists. Compared with our earlier study's examination of six individual dimensions, we investigated the patient-reported distributions of responses for the dimensional comparisons of all 13 individual dimensions of health for both instruments. Consequently, this study included an additional four (of the five) psychosocial domains of health for the AQoL-8D's classification system. 631

This current study particularly highlighted the depth and breadth of the AQoL-8D's classification system as compared to the EQ-5D-5L. Table 2 and Appendix 1 (see the ESM), coupled with schematic representations (Figure 1a–c) of the dimensional comparisons, revealed that the AQoL-8D assessed and captured HRQoL across the broad classification system and through the levels (1 to 4–6) (there were no reported responses for level 6 for the AQoL-8D) given the relative dispersion of participants' responses away from perfect health. This is particularly highlighted with many of the responses for the EQ-5D-5L at level 1 (perfect health/ceiling effect) and level 2, compared to the AQoL-8D only recording just over half of the responses at levels 1 and 2. These findings support the superior discriminant sensitivity of the AQoOL-8D across the individual dimensions of physical and psychosocial health for the study population and as assessed in our previously published work [9].

This study's dimensional comparisons also found the individual dimension that revealed the most similar distribution for both instruments was Pain/Discomfort (EQ-5D-5L) and Pain (AQoL-8D). Therefore, our study's results suggest that both instruments were sensitive to the individual health domain of pain for the study population. Nevertheless, the AQoL-8D provided evidence of change in other domains of health that could be affected by pain, such as sleep, which impacts the Mental Health dimension.

Another key finding of our current study was that the pre- and postoperative summary utility valuations for the EQ-5D-5L were substantially higher (and indeed approached general population norms after surgery) than the summary utility valuations of the AQoL-8D. The AQoL-8D's relatively low preoperative and 3-month postoperative summary utility valuation revealed two important findings: first, the instrument's superior discriminant sensitivity relative to the EQ-5D-5L for the study population due to the AQoL-8D's ability to preferentially capture domains of health that are relevant for the study population; and second, the substantially lower (particularly preoperative) HRQoL for the long-term publicly waitlisted bariatric surgery patients. These findings also accord with evidence that suggests in practice all MAUIs which purport to measure utility give numerical values that differ significantly [12, 41].

5.4.2 Utility valuations

Another key finding of our current study was that change in global utility valuations from before to 3 months after bariatric surgery exceeded the established minimal important differences for both instruments, and for the EQ-VAS. The instruments' summary utility valuations highlighted these long-term waitlisted bariatric surgery patients' considerably diminished physical and psychosocial health status before surgery, and the postoperative summary utility valuations revealed a clinical short-term improvement within the 3-month timeframe. Nevertheless, as discussed previously, compared to the EQ-5D-5L, the AQoL-8D revealed substantially lower pre- and postoperative utility valuations that did not approach population norms.

In particular, this study highlighted the substantially diminished preoperative AQoL-8D utility valuation for our study population. To provide a comparative perspective of the severity of our study population's diminished health state, a recent investigation that used data from a multinational (Australia, Canada, Germany, Norway, the UK and USA) cross-sectional survey found that for composite study populations of people with cancer or heart disease, the AQoL-8D mean (SD) utility valuation for cancer was 0.655 (0.22), and for heart disease, it was 0.667 (0.23) [48].

Therefore, our current study's findings particularly revealed that the preoperative AQoL-8D utility valuation for our cohort of severely obese long-term waitlisted patients was over 0.15 utility points less than that for a study population with cancer or heart disease. In other words, people who languish for long periods on the public waiting list can endure the same substantially diminished HRQoL status as someone with metastatic cancer or prolonged heart disease.

As an independent measure of HRQoL, there is emerging literature that suggests that utility valuations could be independent predictors of health outcomes. A study that investigated the predictive qualities of utility valuations derived from the EQ-5D in patients with diabetes found that they were useful in predicting for health events, including cardiovascular events (e.g. stroke, hospitalisation for angina), other major diabetes-related complications (e.g. heart failure, amputation, renal dialysis and lower extremity ulcer) and death from any other cause [21]. Bariatric surgery patients carry complex physical and psychosocial comorbidity loads, and the assessment of utility valuations in routine clinical care could provide a better understanding of this complexity at an individual patient level, informing preoperative and ongoing postoperative care. Prediction is more likely to be accurate when the instrument used for prediction takes account of the full range of the complex physical and psychosocial problems associated with the problem. Our study's findings suggest that the AQoL-8D is more likely to provide correct prediction than the EQ-5D-5L.

5.4.3 AQoL-8D's individual and super dimension scores

Another key finding of our current study was the substantially lower AQoL-8D dimensional scores before surgery and improvements in these dimensional levels after surgery. Happiness and Coping improved the most after surgery and indeed approached population norms. Additionally, Self-worth also revealed a substantial change. All other individual dimensions improved, but did not substantially approach population norms. Recent evidence has found that body weight is only one contributing factor to the complex physical and psychosocial HRQoL needs of bariatric surgery patients [8].

5.4.4 Integrating patient-reported outcomes in clinical practice

The International Society for Quality of Life Research has developed a clinical users guide to encourage the routine collection of PROs which "are rarely collected in routine clinical practice" [49]. Recent evidence has also found that integrating PROs in clinical practice has the potential to enhance patient-centred care. Within this broader and evolving context of patient-centredness in clinical care, our exploratory study highlighted the clinical relevance of MAUI analyses for long-term waitlisted patients who subsequently undergo bariatric surgery.

This study found that psychosocial health drove a relatively lower utility valuation for the AQoL-8D, despite clinical improvements. We suggest that bariatric clinicians could also further investigate and subsequently integrate and implement utility valuation's predictive qualities, and individual and super-dimension scores to further enhance patient-centred clinical care. Further studies could assess the feasibility of adopting a MAUI that preferentially captures and assesses physical and psychosocial HRQoL into the routine clinical assessment of these patients. We previously identified in our earlier published work that the AQoL-8D preferentially captured physical and psychosocial health for patients who had undergone bariatric surgery (in the longer term) [9], a position reinforced by our current analysis. Through MAUI analyses, our current study established clinically significant changes in psychosocial health (albeit from a relatively low baseline to post-surgical dimensional scores that were still relatively low) that warrant additional attention after surgery to improve overall postoperative health. Additionally, our current study's dimensional comparisons highlighted the EQ-5D-5L's relative insensitivity in distinguishing between health states close to full (or perfect) health for long-term waitlisted patients who had very recently undergone bariatric surgery.

5.4.5 Limitations

There are limitations to our study. The first limitation is small sample size. Nevertheless, our study was exploratory and we were provided with a novel opportunity to recruit participants from the long-term waitlisted patients subsequently fast-tracked for bariatric surgery through a government policy decision to reduce waiting lists. Our exploratory study of long-term waitlisted patients should inform larger confirmatory studies to test the validity of the EQ-5D-5L and AQoL-8D, and the short-term health impacts for long-term waitlisted patients. Nevertheless, we also acknowledge that a substantial commitment would need to be made at the public policy level to recruit a similar cohort of long-waiting patients. Other MAUIs such as the SF-6D could also be considered for larger confirmatory studies. The second limitation is that all participants were operated on by the same surgeon in the same hospital. This could affect the generalisability of our results if scaled up to all bariatric surgery patients. On the other hand, this circumstance could also be a strength given the homogenous nature of the sample.

The third limitation is that there is no control arm in the study. The observational nature of our study did not enable the recruitment of a control arm to elicit utility valuations; however, the key objective of this study was to compare the two MAUI. The final limitation is that the sample is at risk of participant selection bias, which could also affect the generalisability of our results.

A relative strength of our study is the high overall response rate of 74% to the questionnaires across the two time points.

The limitations of our study concur with our complementary study of the same cohort [11]

5.5 Conclusions

Within the small sample limitations of our exploratory study and to address the key objective of our study, which was a head-to-head comparison of the instruments, compared to the EQ-5D-5L, the AQoL-8D preferentially captured the complex physical and psychosocial short-term health changes for long-term publicly waitlisted patients who very recently underwent bariatric surgery. Importantly, researchers should understand a MAUIs descriptive/classification system and the innate sensitivities of the MAUI in regard to the particular study population, in this case long-term waitlisted patients who then undergo bariatric surgery. We recommend the AQoL-8D as a preferred MAUI over the EQ-5D-5L for bariatric surgery patients, given their complex physical and psychosocial needs.

In regard to our secondary objectives, utility valuations and dimensional scores (AQoL-8D only) revealed substantially lower health status for long-term waitlisted patients both before and after surgery, but with clinical short-term HRQoL improvements even 3 months after surgery. AQoL-8D preoperative utility valuation particularly revealed our study population's HRQoL was substantially lower than that of people with cancer or heart disease.

Dimensional comparisons, utility valuations, and individual and super-dimension scores could provide the clinician with both individual patient and cohort valuations that could lead to improved patient-centred care by identifying health domains requiring additional attention.

Routine integration of comprehensive MAUI analyses could provide clinicians with additional and independent assessments and predictors of HRQoL and in turn, enhance patient-centred care.

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Appendix 5A: Publication of “An exploratory study: a head-to-head comparison of the EQ-5D-5L and AQoL-8D for long-term publicly waitlisted patients before and 3 months after bariatric surgery”.

PharmacoEconomics Open
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ORIGINAL RESEARCH ARTICLE

An Exploratory Study: A Head-to-Head Comparison of the EQ-5D-5L and AQoL-8D for Long-Term Publicly Waitlisted Bariatric Surgery Patients Before and 3 Months After Bariatric Surgery

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Abstract

Background Choice of a multi-attribute utility instrument (MAUI) that appropriately assesses an intervention's health-related quality-of-life (HRQoL) impacts is a vital part of healthcare resource allocation and clinical assessment.

Objective Our exploratory study compared the EuroQol (EQ)-5D-5L and Assessment of Quality of Life (AQoL)-8D MAUIs, which were used to assess the effect of bariatric surgery for a cohort of long-term publicly waitlisted, severely obese patients.

Methods The study was conducted at the Hobart Private Hospital (Tasmania, Australia). To compare the sensitivity and instrument content of the two MAUIs, we used dimensional comparisons by investigating the distribution of patient-reported responses (number/percentage) across the MAUIs' levels and dimensions; summary health-state utility valuations (utilities); and individual/super-dimension scores (AQoL-8D) to investigate discriminatory power and HRQoL improvements preoperatively and 3 months postoperatively.

Results Participants' ($n = 23$) overall MAUI completion rate was 74%. Postoperative total weight loss was 9.9%. EQ-5D-5L utilities were relatively higher pre- and post-operatively than AQoL-8D utilities [mean standard deviation (SD) EQ-5D-5L 0.70 (0.25) to 0.80 (0.25); AQoL-8D 0.51 (0.24) to 0.61 (0.24)]. AQoL-8D Psychosocial super dimension was relatively low postoperatively [0.37 (0.25)], driving the instrument's lower utility. These results were supported by the dimensional comparisons that revealed an overall greater dispersion for the AQoL-8D. Nevertheless, there were clinical improvements in utilities for both instruments. AQoL-8D utilities were lower than population norms; not so the EQ-5D-5L utilities. The AQoL-8D dimensions of Happiness, Coping, and Self-worth improved the most.

Conclusions AQoL-8D more fully captured the impact of obesity and bariatric surgery on HRQoL (particularly psychosocial impacts) for long-term waitlisted bariatric surgery patients, even 3 months postoperatively. AQoL-8D preoperative utility revealed our population's HRQoL was lower than people with cancer or heart disease.

Electronic supplementary material The online version of this article (doi:10.1007/s41669-017-0060-1) contains supplementary material, which is available to authorized users.

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Key Points for Decision Makers

The Assessment of Quality of Life (AQoL)-8D may have superior discriminatory sensitivity compared to the EuroQol (EQ)-5D-5L for long-term waitlisted severely obese bariatric surgery patients.

There is potential for sub-optimal healthcare resource allocation if the selected multi-attribute utility instrument does not appropriately assess health-related quality-of-life (HRQoL) impacts for the bariatric surgery study population.

As an important and increasingly prevalent study population of bariatric surgery patients who inherently carry complex physical and psychosocial HRQoL needs, long-term waitlisted severely obese bariatric surgery patients showed improvements in HRQoL even 3 months postoperatively.

1 Introduction

Demand for publicly funded bariatric care in many countries is high; however, capacity is limited by healthcare funding decisions. Consequently, bariatric (metabolic, obesity or weight-loss) surgery waiting lists are long [1, 2]. Prolonged delays generally exist for people waitlisted for primary bariatric surgery in public health systems in many countries, including Australia [3–5].

Whilst it is acknowledged that these protracted multi-year wait times are detrimental to the bariatric surgery candidate's physical and psychosocial health [2, 6, 7], recent evidence has established that weight status is just one factor contributing to the complex health-related quality-of-life (HRQoL) needs of people who have received bariatric surgery [8, 9]. Nevertheless, there is a paucity of quantitative evidence regarding HRQoL impacts for long-term waitlisted bariatric surgery patients who have experienced multiyear wait times on public waiting lists and then undergo bariatric surgery [10, 11].

Multi-attribute utility instruments (MAUIs) are a HRQoL assessment tool designed to rapidly and conveniently assess and capture an individual's health-state utility values through application of pre-established formulae/weights to the array of responses obtained on the MAUI's questionnaire [9]. A MAUI is developed and defined with particular characteristics, including the number of questionnaire items; the depth and breadth of the descriptive/classification system; the number of health states described; the number of individual and super dimensions (if there are super dimensions); and the algorithmic range.

For example, the number of health states described for the EuroQol (EQ)-5D-3L and 5L, Health Utilities Index (HUI) 3, 15D, Short-Form 6 Dimension (SF-6D), Quality of Well-Being (QWB) and Assessment of Quality of Life (AQoL)-8D MAUIs range from 243; 3125; 972,000; 3.1×10^{10}; 18,000; 945; and 2.4×10^{23}, respectively [12]. Additionally, many MAUIs target physical health within their descriptive/classification systems. For example, for the EQ-5D-5L, one of its five dimensions relates to psychosocial health (Anxiety/Depression) and four out of five relate to physical health (Mobility, Self-care, Usual Activities and Pain) [13]. In contrast, for the AQoL-8D, three of the instrument's eight dimensions relate to physical health (Independent Living, Senses and Pain), and five of the eight dimensions relate to psychosocial health (Coping, Relationships, Self-worth, Happiness and Mental Health), and 25 of the 35 items (questions) inform the AQoL-8D's five psychosocial dimensions [14, 15]. The SF-6D describes six dimensions, namely Physical Functioning, Role Limitations, Social Functioning, Pain, Mental Health and Vitality [12, 16]. Both the AQoL-8D and SF-6D describe composite physical and psychosocial dimensions, namely the Physical and Psychosocial super dimensions (AQoL-8D), and the Physical and Mental Component Summaries (SF-6D) [14, 17].

A small number of MAUIs dominate the economic evaluation literature. These include the EQ-5D-3L (precursor to the EQ-5D-5L), HUI 3 and SF-6D. A review of 1663 studies between 2005 and 2010 found that these three instruments accounted for 63, 9.9, and 8.8% of the total, respectively [12]. Four other instruments in the review, the 15D, HUI 2, AQoL, and QWB, were used in 7, 4.6, 4.2, and 2.5% of the studies, respectively [18].

A recent cross-sectional study of patients who had received bariatric surgery in the private healthcare system many years previously [median [interquartile range (IQR)] 5 (3–8) years] found that the AQoL-8D and EQ-5D-5L instruments were not interchangeable for the study population [9]. Another recent study that investigated the 1-year health impacts for long-term waitlisted bariatric surgery patients (and complementary to this study using the same cohort of patients), suggested that the AQoL-8D preferentially captured HRQoL for the study population 1 year after surgery [11]. Importantly, this 1-year study did not directly compare the distributions of patient-reported responses across the depth and breadth of the MAUIs' dimensions of health (dimensional comparisons) [11]. As a single MAUI instrument, the AQoL-8D captures the vast majority of domains considered crucial for people who are considering, or who have undergone, bariatric surgery [9].

The choice of MAUI should be influenced by the sensitivity of the instrument to a patient group's health profile [9, 12]. If the choice of instrument does not appropriately capture and assess the individual's and study population's health profiles (particularly for complex physical and psychosocial HRQoL), vital healthcare information about a clinical intervention's health impact will be omitted from important resource allocation and planning decisions [9].

Utility valuations are key health economic metrics that are an input measure in the assessment of quality-adjusted life years (QALYs) [19]. Utility valuations measure the strength of preference for a particular health state and are represented as a number on a scale where 1.0 represents the best possible health state and 0.0 represents death. In principle, values less than zero are possible when a health state is worse than death [20]. Utility values assessed by MAUIs are not equivalent, with the difference between the descriptive/classification systems of the MAUIs the principal determinant [12]. Additionally, differences in descriptive/classification systems are estimated to explain an average of 66% of the difference between utilities obtained by MAUIs, and 81% of the difference between the utilities of the EQ-5D-5L and AQoL-8D [12].

MAUIs were not initially developed for clinical use; however, utility valuations can also be used to inform and/or predict clinical outcomes [21]. Clinicians have found that measuring utilities is of benefit to patient–clinical assessment, relationships, communication, and management [22]. Many MAUIs (including the EQ-5D-5L and 3L, AQoL-4D, SF-6D, 15D and HUI) report minimal clinically important differences or minimal important differences for their utility valuations [23–28]. A minimal clinically important difference is the smallest difference in score in the outcome of interest that patients perceive as beneficial and which would mandate a clinical change in the patient's management (both individually and collectively for a particular study population) [22, 23, 29, 30].

There is a paucity of evidence regarding short-term HRQoL impacts for people who have received bariatric surgery [31, 32]. A study published in 2007 provided 3-month (range 3–6 months) HRQoL impacts of bariatric surgery using the SF-36 [33]. A second study published in 2001 provided 1-, 3- and 6-month HRQoL impacts of bariatric surgery using the SF-36, bariatric analysis and reporting outcome system (BAROS) and Moorhead-Ardelt quality-of-life questionnaires [34]. Both studies found short-term improvements in the quality of life scores (however, these studies did not generate, nor investigate, utility valuations) after bariatric surgery.

Whilst it is acknowledged that integrating patient-reported outcomes (PROs) in clinical practice has the potential to enhance patient-centred care [35], PROs are not yet routinely collected in bariatric care. A recent systematic review that identified and investigated prospective bariatric surgery studies that used validated PRO measures found that for PRO data to influence practice, well-designed and reported studies are required [36]. In turn, there is a potential for MAUIs to address this key gap regarding PROs in bariatric care subject to the particular MAUI's capacity to capture, assess and describe the relevant health states of the study population.

The main objective of this exploratory study was to directly compare the discriminatory power of two different MAUIs, namely the EQ-5D-5L and the AQoL-8D, which were used to assess the effect of bariatric surgery using a cohort of long-term publicly waitlisted, severely obese patients who underwent bariatric surgery as part of a government policy initiative to reduce waiting lists. As a secondary objective, we also aimed to investigate the role of the two MAUIs in the analysis of individual patient health states.

The EQ-5D suite of instruments dominates the clinical and economic literature, including that for bariatric surgery [14, 18]. Nevertheless, the AQoL-8D has been shown to have preferential psychometric properties compared to comparative MAUIs in study populations where the assessment of psychosocial health status is crucial, for example, intensive care unit (ICU) admissions (compared with SF-6D) [22] and people who had undergone bariatric surgery (compared with the EQ-5D-5L) [9, 11]. Additionally, a recent study that presented results from one of the broadest comparative surveys in terms of the range of diseases (arthritis, asthma, cancer, depression, diabetes, hearing loss and heart disease) and six MAUIs (EQ-5D-5L, SF-6D, HUI 3, 15D, QWB and AQoL-8D), and countries (Australia, the USA, the UK, Canada, Norway, and Germany) found that the AQoL-8D is the most sensitive instrument for measuring mental health [37]. This study also found that the pain component of the EQ-5D-5L has a greater impact than it does in any other instrument, and that the EQ-5D-5L is the most sensitive instrument for measuring pain [37].

Our exploratory study also investigated the relative magnitudes of the global utility valuations [12], clinical improvements of the utility valuations for both instruments, and also the impacts on individual domains of health through the AQoL-8D's individual and super-dimension scores.

In parallel with our previously published study that investigated the 1-year health impacts in long-term waitlisted patients [11], this current study aimed to investigate the distribution of the patient-reported responses of the two MAUIs for this population of public healthcare long-waiting bariatric surgery patients who inherently carry complex physical and psychosocial HRQoL needs.

2 Methods

2.1 Study Design

2.1.1 Recruitment of Participants

Recruitment of our study participants is described in detail in our previously published study [11]. In summary, a Tasmanian government policy decision was made in 2014 to allocate additional and targeted public funds to provide morbidly obese, long-term waitlisted patients with bariatric surgery in 2015 [38]. All participants underwent laparoscopic adjustable gastric band (LAGB) surgery by the same surgeon in the Hobart Private Hospital. Laparoscopic banding was carried out using Apollo APS or APL bands, with adjustment ports attached to the left anterior rectus sheath [39]. Postoperative fluid diets were maintained for 3 weeks, with subsequent transition to normal foods, accompanied by instruction on eating technique and exercise.

All data were de-identified. Ethics approval was granted by the University of Tasmania's Health and Medical Human Research Ethics Committee (HMHREC) before our study's recruitment of participants.

2.1.2 The Multi-attribute Utility Instruments and Questionnaire Completion

The selection and attributes of the EQ-D-5L and AQoL-8D MAUIs used in this study have previously been described in detail [11]. Another earlier study comparing the EQ-5D-5L and the AQoL-8D MAUIs for people who had undergone LAGB surgery many years previously provided a detailed summary of the divergent characteristics of the two purposively selected MAUIs [9, 11]. In summary, the two markedly different MAUIs were selected on the following basis: the EQ-5D-5L is the internationally prevalent instrument in economic evaluation (including the economic evaluation of bariatric surgery) [40]; four of the five instrument's health domains/classifications (and items) focus on physical HRQoL; and it takes less than 1 min to complete the EQ-5D-5L's questionnaire [13]. The EQ-5D-5L also contains a visual analogue scale (EQ-VAS) [22]. In contrast, the AQoL-8D's classification system is supported by psychometric principles and testing, and 25 of the instrument's 35 items capture and assess five (from eight) psychosocial domains of health, and three physical domains of health. The AQoL-8D describes billions of health states and takes 5 min to complete [14, 15, 41].

Participants were asked to self-complete both instruments' questionnaires before their bariatric surgery at the pre-admission preoperative clinics and at 3 months postoperatively. Postoperative questionnaires were mailed out for self-completion with an explanatory cover letter and reply-paid envelope enclosed. We evaluated EQ-5D-5L and AQoL-8D questionnaire completion by assessing the overall proportion of participants who completed the questionnaire(s) at the study's two time points for whom an individual utility value could be generated.

2.2 Data Analysis

Participants with patient-reported HRQoL assessments for one or both instruments, for at least one time point where the MAUI algorithm (either instrument) could generate the instrument's utility valuations or scores were included in the analyses.

Descriptive baseline socio-demographic, clinical data, utility valuations and dimensional scores were presented as mean [standard deviation (SD)] and/or median (IQR) for continuous variables and frequency (%) for categorical variables. Body mass index (BMI) was calculated as weight (kg)/[height (m^2)] and classified as obese (BMI 30–34.9 kg/m^2), severely obese (BMI 35–39.9 kg/m^2), morbidly obese (BMI 40–49.9 kg/m^2), and super obese (BMI $\geq$50 kg/m^2) [42].

2.2.1 Discriminant Sensitivity: Dimensional Comparisons (Both Instruments) and Dimensional Scores (AQoL-8D)

The relative discriminatory power of the instruments was investigated using two methodologies.

First, we calculated the distribution of participant responses across the levels and dimensions (the depth and breadth) of both instruments. This was achieved by collating the participant-reported response for each item and then calculating the percentage distribution of responses for each dimension [9, 16]. To illustrate, for the EQ-5D-5L individual dimension of Anxiety/Depression, the numbers of participants who gave each response level (1, 2, 3, 4 or 5) were converted to a percentage of the total number of participants in order to derive a 'five-level frequency distribution'. Detailed calculations for each item and dimension are provided in Appendix 1 [see the electronic supplementary material (ESM)]. Additionally, schematic representations of the dimensional comparisons were expressed as a percentage by calculating the average percentage before and after surgery. For example, the schematic representation of the physical dimensions of both instruments compared the average score of Mobility, Self-care, Usual Activities and Pain for the EQ-5D-5L and Independent Living, Sense and Pain for the AQoL-8D for each level before and after surgery.

Appendix 5A: Publication of "An exploratory study: a head-to-head comparison of the EQ-5D-5L & AQoL-8D for long-term publicly waitlisted bariatric surgery patients before & 3 months after bariatric surgery".

Second, impacts on the individual domains of physical and psychosocial HRQoL were investigated through the AQoL-8D's summary scores for the eight individual dimensions and two super dimensions. The EQ-5D-5L generates a single utility valuation for an individual; however, it does not generate individual or summary scores for each and every one of its five separate dimensions.

2.2.2 *Analyses of Summary Utility Valuations and EQ-VAS Scores*

Utility valuations were generated for the EQ-5D-5L using the most recent UK value based on directly elicited preferences, the valuation ranging from −0.281 to 1.0 utility points [43, 44]. All five questions require a valid response to generate a utility score. EQ-5D population norms are sourced from UK data because there are no available Australian population norms [45]. For the AQoL-8D, we used the current version of the scoring algorithm incorporating Australian weights published on the AQoL group's website (http://www.aqol.com.au) (valuation range +0.09 to 1.0 utility points). For the AQoL-8D's scoring algorithm, an overall utility valuation can be generated with ten missing values scattered over all dimensions. Australian population norms were sourced from recently published valuations [41]. Individual and super-dimensional scores are also generated with the AQol-8D's scoring algorithm.

A minimal clinically important difference (or minimal important difference) is the smallest difference in score in the outcome of interest which patients perceive as beneficial and which would mandate a change in the patient's management [23, 29, 30]. A recently reported composite minimal important difference for the EQ-5D-5L for chronic health conditions was reported as 0.04 utility points [46]. There is no established minimal important difference for the AQoL-8D; however, a minimal important difference for the AQoL-4D has previously been reported as 0.06 utility points, with a 95% confidence interval of 0.03–0.08 utility points [24]. This study conservatively adopted the upper bound of 0.08 utility points as the proxy minimal important difference for comparison of the pre- and postoperative AQoL-8D utility valuations. The established minimal important difference for the EQ-VAS is 10 points [47]. It has been suggested that with the expanded use of HRQoL endpoints (for example, analyses of utility valuations and scores within vastly different MAUI classification systems), the interpretation of HRQoL in the context of minimal important differences is imperative [23]. In turn, our study has included the interpretation of minimal important differences in its comparison of the EQ-5D-5L and AQoL-8D MAUIs.

Statistical analyses were undertaken using IBM SPPS (version 22) or R (version 3.0.2).

3 Results

3.1 Participants' Characteristics and Questionnaire Completion

Twenty-three participants were recruited to the study. For these participants, mean (SD) age was 50 (10) years, 43% were males, and mean (SD) and median (IQR) time on the public waiting list for bariatric surgery was 6.5 (2.0) and 6.3 (5.0–7.8) years, respectively.

Table 1 provides pre- and postoperative results for BMI, percentage total weight lost and percentage excess weight lost. Before surgery 39% of participants were classified as super obese (BMI ≥50 kg/m^2) and 57% were classified as morbidly obese (BMI 40–49.9 kg/m^2). After surgery, there was a 26% reduction in the super-obesity category. Similarly, after surgery, the morbidly obese category was reduced by 17%.

In regard to questionnaire completion, there was a 74% completion rate of questionnaires overall [Tables 2, 3 and 4; Appendix 1 (see the ESM)].

3.2 Sensitivity: Dimensional Comparisons

The relative discriminatory power of the instruments was investigated using the dimensional comparisons outlined in Sect. 2.2.1.

Table 2 (supported by Appendix 1 in the ESM) presents the 'before' and 'after' surgery distribution of participant responses for both MAUIs' 13 individual dimensions/domains of health across levels 1–5 (EQ-5D-5L) and levels 1 through to 4, 5 or 6 (AQoL-8D). Figure 1a–c also provide a schematic representation of the comparative distribution of the participants' responses across levels 1–6 for all dimensions (Fig. 1a), and for the physical dimensions of health for both instruments (EQ 5D-5L: Mobility, Self-care, Usual Activities and Pain; AQoL-8D: Independent Living, Senses and Pain) (Fig. 1b), and the psychosocial dimensions of health for both instruments (EQ-5D-5L: Anxiety/Depression; AQoL-8D: Coping, Mental Health, Relationships, Self-worth, Happiness) (Fig. 1c).

None of the participants responded to level 6 for the AQoL-8D items that provided for a level 6 response [namely Independent Living (one item), Senses (two items: vision and hearing), Mental Health (one item) and Relationships (one item)] (Table 2 and Appendix 1). Table 2 and Fig. 1a–c (supported by Appendix 1) revealed a more even dispersion of participant responses for the AQoL-8D than the EQ-5D-5L both pre- and postoperatively. The AQoL-8D more clearly distinguished between health states that are close to full health for the study population (Table 2, Fig. 1a–c, Appendix 1).

Table 1 Number of participants ($n = 23$) in obesity categories before and after surgery

	Before surgery	After surgery*	Change
BMI			
Mean (SD)	49.3 (9.4)	43.5 (7.2)	−5.8
Median (IQR)	45.5 (41.6–55.4)	43.2 (38.7–49.6)	−2.3
BMI (n, %)			
BMI ≥30–34.9 kg/m^2 (class I)	(1, 4%)	(2, 9%)	(+1, +6%)
BMI ≥35–39.9 kg/m^2 (class II)	0	(7, 30%)	(+7, +33%)
BMI ≥40–49.9 kg/m^2 (class III)	(13, 57%)	(9, 39%)	(−4, −17%)
BMI ≥50 kg/m^2**	(9, 39%)	(3, 13%)	(−6, −26%)
Weight (kg)			
Mean (SD)	139.7 (31.4)	125.9 (26.9)	−13.8
Median (IQR)	134.0 (118.8–161.5)	124.5 (106.9–142.2)	−8.1
% Total weight lost			
Mean (SD)	NA	9.9 (6.2)	NA
Median (IQR)	NA	11.0 (3.7–15.0)	NA
% Excess weight lost			
Mean (SD)	NA	21.5 (13.1)	NA
Median (IQR)	NA	24.7 (12.6–28.2)	NA

BMI body mass index, *IQR* interquartile range, *NA* not applicable, *SD* standard deviation

*$N = 21$; 2 participants' 3-month weight not available

**Super obese (≥50 kg/m^2)

More specifically, postoperatively participants recorded 80% (76/95) of responses for the EQ-5D-5L at level 1 (perfect health: I have no problems) and level 2 (I have slight problems), the highest recorded response at level 1 being 74% for Self-care (decreased from 81% before surgery) (Table 2; Appendix 1). These results highlight the EQ-5D-5L's inability to distinguish between health states close to full/perfect health (utility score 1.0). Additionally, for the EQ-5D-5L's only psychosocial dimension of health (Anxiety/Depression), participants did not record responses at level 4 (I am severely anxious or depressed), nor level 5 (I am extremely anxious or depressed), indicating that the EQ-5D-5L's only psychosocial dimension is relatively limited. Before surgery, only 6% of participants recorded both levels 4 and 5 for Anxiety/Depression (Table 2, Appendix 1, and Fig. 1c). Participants recorded responses at level 4 (16%) for one of the EQ-5D-5L's individual dimensions (Pain) after surgery (Table 2; Appendix 1).

In contrast, participants' postoperative responses to the AQoL-8D questionnaire were less concentrated in the upper levels (i.e. more evenly dispersed across the levels), with only 58% (365/630) of responses recorded at levels 1 and 2 (Table 2, Fig. 1a, and Appendix 1), the highest recorded response at level 1 being 41% for Senses.

Participants also recorded responses at level 4 for all the AQoL-8D's individual dimensions, and participants also recorded responses at level 5 for both Pain and Mental Health. Additionally, the lowest percentage of participants scored at level 1 for the AQoL-8D's individual dimensions of Happiness (15%), Coping (19%) and Mental Health (26%) (Table 2; Appendix 1). Nevertheless, Happiness and Coping substantially improved from before surgery to 3 months after surgery and approached population norms (Table 3), and this result is also revealed with the improvement of participants' preoperative scores at level 1 in Happiness (from 3% to 15%) and Coping (from 11% to 19%) (Table 2; Appendix 1).

The individual dimension that had the most similar distribution for both instruments across levels 1–5 was Pain/Discomfort for the EQ-5D-5L (level 1: 26%, level 2: 32%, level 3: 26%, level 4: 16% and level 5: 0%) and Pain for the AQoL-8D (level 1: 35%, level 2: 19%, level 3: 31%, level 4: 13% and level 5: 2%) (Table 2; Appendix 1). Three of the 35 AQoL-8D items contribute to the dimension of Pain. These items capture and assess how often the respondent suffers for the first Pain item 'serious pain', for the second Pain item the severity of 'pain or discomfort', and for the third Pain item of how often pain interferes with usual activities. The EQ-5D-5L individual dimension of Pain/Discomfort assesses the level of severity of pain/discomfort (no pain/discomfort, slight, moderate, severe, extreme).

3.3 Sensitivity: Comparison of Changes in Utility Valuations

Table 4 provides summary statistics for the changes in both instruments' utility valuations preoperatively to 3 months

Appendix 5A: Publication of “An exploratory study: a head-to-head comparison of the EQ-5D-5L & AQoL-8D for long-term publicly waitlisted bariatric surgery patients before & 3 months after bariatric surgery”.

Table 2 Dimensional comparisons of response rates (%) for all individual dimensions of the EQ-5D-5L and AQoL-8D before surgery and 3 months after bariatric surgery

	EQ-5D-5L						AQoL-8D							
							Physical super dimension			Psychosocial super dimension				
	Mobility	Self-care	Usual Activities	Pain/ Discomfort	Anxiety/ Depression		Independent Living (4 items)	Pain (3 items)	Senses (3 items)	Coping (3 items)	Mental Health (8 items)	Happiness (4 items)	Relation-ships (7 items)	Self-worth (3 items)
Before surgery ($n = 16$)						Before surgery ($n = 15$)								
Level 1	38%	81%	50%	31%	25%	Level 1	27%	29%*	31%	11%	19%*	3%	24%*	18%*
Level 2	25%	6%	13%	13%	38%	Level 2	17%	20%	40%	36%	23%	33%	31%	20%
Level 3	31%	13%	25%	25%	25%	Level 3	30%	27%	29%	29%	36%	42%	29%	33%
Level 4	6%	0	13%	31%	6%	Level 4	18%	18%	0	20%	15%	17%	9%	24%
Level 5	0	0	0	0	6%	Level 5	8%	7%	0	4%	8%	5%	8%	4%
Level 6	NA	NA	NA	NA	NA	Level 6	0	NA	0	NA	0	NA	0	NA
After surgery ($n = 19$); % (% point change†)						After surgery ($n = 18$)								
Level 1	53% (+ 15)	74% (− 7)	53% (+ 3)	26% (− 5)	47% (+ 22)	Level 1	26% (− 1)	35% (+ 6)	41% (+ 10)	19% (+ 8)	26% (+ 7)	15% (+ 12)	33% (+ 9)	30% (+ 12)
Level 2	26% (+ 1)	21% (+ 15)	32% (+ 19)	32% (+ 19)	37% (− 1)	Level 2	31% (+ 14)	19% (− 1)	30% (− 10)	44% (+ 8)	24% (+ 1)	38% (+ 5)	34% (+ 3)	26% (+ 6)
Level 3	21% (− 10)	5% (− 8)	16% (− 9)	26% (+ 1)	16% (− 9)	Level 3	29% (− 1)	31% (+ 4)	26% (− 3)	24% (− 5)	44% (+ 8)	39% (− 3)	23% (− 6)	31% (− 2)
Level 4	0 (− 6)	0 (0)	0 (+ 13)	16% (− 15)	0 (− 6)	Level 4	14% (− 4)	13% (− 5)	4% (+ 4)*	13% (− 7)	4% (− 11)*	8% (− 9)	10% (+ 1)	13% (− 11)
Level 5	0 (0)	0 (0)	0 (0)	0 (0)	0 (− 6)	Level 5	0 (− 8)	2% (− 5)	0 (0)	0 (0)	1% (− 7)	0 (− 5)	0 (− 8)	0 (− 4)
Level 6	NA	NA	NA	NA	NA	Level 6	0 (0)	NA	0 (0)	NA	0	NA	0 (0)	NA

Detailed calculations supporting Table 2 are contained in Appendix 1 (see the electronic supplementary material)

AQoL-8D items: AQoL-8D Independent Living: 4 AQoL items: household tasks levels 1–5, getting around levels 1–6, mobility levels 1–6, self-care levels 1–5; AQoL-8D Pain: 3 AQoL items: frequency of pain levels 1–4, degree of pain levels 1–4, pain interference levels 1–5; AQoL-8D Senses: 3 AQoL items: vision levels 1–6, hearing levels 1–6, communication levels 1–4; AQoL-8D Coping: 3 AQoL items: energy levels 1–5, being in control levels 1–5, coping with problems levels 1–5; AQoL-8D Mental Health: 8 AQoL items: feelings of depression levels 1–6, trouble sleeping levels 1–5, feelings of anger levels 1–5, self-harm levels 1–5, feeling despair levels 1–5, worry levels 1–5, sadness levels 1–5, tranquillity/agitation levels 1–5; AQoL-8D Happiness: 4 AQoL items: contentment levels 1–5, enthusiasm levels 1–5, degree of feeling happiness levels 1–5, pleasure levels 1–5; AQoL-8D Relationships:7 AQoL items: relationship with family and friends levels 1–6 and levels 1–5, social isolation levels 1–5, social exclusion levels 1–5, intimate relationship levels 1–5, family role levels 1–5, community role levels 1–4; and AQoL-8D Self-worth:3 AQoL items: feeling like a burden levels 1–5, worthlessness levels 1–5, confidence levels 1–5

AQoL Assessment of Quality of Life, *NA* not applicable

*Columns add to 99 or 101 per cent due to rounding

†Figure in brackets after surgery reflects the percentage point change (i.e. 'after surgery' minus 'before surgery')

Table 3 Comparison of AQoL-8D individual and super-dimension scores before surgery and 3 months after surgery (total participants $n = 23$), and Australian population norms for total population and 45–54-year age group

AQoL-8D individual and super dimensions	Before bariatric surgery ($n = 15$)			After bariatric surgery ($n = 18$)			Improvement in mean score preoperatively to 3 months postoperatively	Australian population norms	
								45–54 years	Total
	Mean (SD)	Min	Max	Mean (SD)	Min	Max	Change	Mean (SD)	Mean (SD)
Dimensions of physical health									
Independent Living	0.69 (0.22)	0.39	1.00	0.75 (0.19)	0.41	1.00	+0.06	0.93 (0.12)	0.94 (0.11)
Senses	0.81 (0.13)	0.56	1.00	0.83 (0.13)	0.59	1.00	+0.02	0.88 (0.10)	0.91 (0.10)
Pain	0.56 (0.34)	0.16	1.00	0.62 (0.32)	0.21	1.00	+0.06	0.84 (0.21)	0.86 (0.19)
Dimensions of psychosocial health									
Happiness	0.65 (0.16)	0.32	0.85	0.75 (0.15)	0.51	1.00	+ 0.10	0.77 (0.16)	0.80 (0.15)
Coping	0.67 (0.15)	0.39	0.96	0.76 (0.15)	0.51	1.00	+ 0.09	0.80 (0.16)	0.83 (0.15)
Relationships	0.62 (0.16)	0.47	1.00	0.67 (0.18)	0.47	1.00	+ 0.05	0.78 (0.16)	0.79 (0.16)
Self-worth	0.65 (0.21)	0.35	1.00	0.76 (0.18)	0.39	1.00	+ 0.11	0.84 (0.16)	0.85 (0.15)
Mental Health	0.54 (0.12)	0.28	0.73	0.60 (0.15)	0.36	0.96	+ 0.06	0.67 (0.17)	0.69 (0.17)
Super-dimensions									
Physical super dimension	0.51 (0.29)	0.18	0.97	0.56 (0.27)	0.22	1.00	+ 0.05	0.79 (0.20)	0.83 (0.18)
Psychosocial super dimension	0.25 (0.15)	0.08	0.49	0.37 (0.25)	0.12	0.97	+ 0.12	0.47 (0.24)	0.50 (0.24)
Utility value for AQoL-8D	0.51 (0.24)	0.20	0.83	0.61 (0.24)	0.29	1.00	+ 0.10	0.77 (0.20)	0.80 (0.19)

Max maximum, *Min* minimum, *SD* standard deviation

Table 4 Summary statistics for EQ-5D-5L and AQoL-8D at baseline (before surgery), difference between the two measures at baseline, and changes in the participants' scores over the 3 months of follow-up (total participants $n = 23$)

	EQ-5D-5L (baseline) ($n = 16$)	EQ-5D-5L (after surgery) ($n = 19$)	EQ-5D-5L change (after surgery–baseline)	AQoL-8D (baseline) ($n = 15$)	AQoL-8D (after surgery) ($n = 18$)	AQoL-8D change (after surgery–baseline)	Difference in baseline/after surgery scores: (EQ-5D-5L–AQoL-8D)	EQ-VAS (baseline) ($n = 16$)	EQ-VAS (after surgery) ($n = 19$)	EQ-VAS change (baseline to 3 months)
Mean	0.70	0.80	0.10	0.51	0.61	0.10	0.19/0.19	57	67	10
SD	0.25	0.25	0	0.24	0.24	0	0.01/0.10	25	24	(1)
Median	0.73	0.84	0.11	0.51	0.58	0.07	0.22/0.29	65	65	0
IQR	0.54–0.91	0.59–0.86	NA	0.29–0.78	0.43–0.78	NA	NA	34–73	48–90	NA
Minimum	0.24	0.46	0.22	0.20	0.29	0.09	0.04/0.17	15	27	12
Maximum	1.00	1.00	0	0.83	1.00	0.17	0.17/0	95	99	4

IQR interquartile range, *NA* not applicable, *SD* standard deviation, *VAS* visual analogue scale

postoperatively. The EQ-5D-5L revealed relatively higher summary utility valuations than the AQoL-8D both before and after surgery. Specifically, the order of magnitude of the EQ-5D-5L's mean utility valuations were 0.19 utility points greater than the mean AQoL-8D utility valuations preoperatively and 3 months postoperatively. The AQoL-8D particularly showed low summary utility valuations before surgery [EQ-5D-5L 0.70 (0.25); AQoL-8D 0.51 (0.24)].

Three months after surgery, the summary utility valuations revealed clinical improvements for both instruments. Nonetheless, the AQoL-8D showed substantially lower postoperative summary utility valuations than the EQ-5D-5L. More specifically, the EQ-5D-5L utility value increased by 0.10 points from mean (SD) 0.70 (0.25) to 0.80 (0.25). Similarly, the AQoL-8D utility value increased by 0.10 points from 0.51 (0.24) to 0.61 (0.24) (Table 4).

After surgery, the EQ-5D-5L utility valuations approached comparable population norms, but not so the AQoL-8D's utility valuations. The UK general population mean for the EQ-5D-5L is 0.86 [45], and for the AQoL-8D the general Australian population norm is 0.80 (0.19), and for the 45–54-year age group, it is 0.77 (0.20) [41] (Table 4).

Table 4 also provides mean (SD) pre- and postoperative EQ-VAS scores of 57 (25) to 67 (24) points, the difference equalling the established EQ-VAS minimal important difference of 10 points.

3.4 AQoL-8D Individual/Super-Dimension Scores

Table 3 provides the AQoL-8D's individual and super-dimension scores before surgery and 3 months after surgery, and the Australian population norms at the individual dimensional level for the general population and the 45–54-year age group. Additionally, Fig. 2a, b provide a schematic representation of the individual and super-dimensional scores compared with the general Australian population norm. The EQ-5D-5L does not generate individual or super-dimension scores.

Improvements were observed for all eight individual dimension scores and the two super-dimension scores even 3 months after surgery. Three months after surgery, the Physical super dimension improved 0.05 points to mean (SD) 0.56 (0.27) points and the Psychosocial super-dimension score improved 0.12 points to 0.37 (0.25) points. Of the eight individual dimensional scores, Self-worth and Happiness improved the most 3 months after surgery by revealing gains of 0.11 points (Self-worth) and 0.10 points (Happiness). The postoperative scores for Happiness 0.75 (0.15) and Coping 0.76 (0.15) also approached both the 45–54-year age group and general population norms. Happiness was only 0.02 points less than the 45–54-year age group population norm and Coping was only 0.04

points less than the 45–54-year age group population norm. Other individual dimensional scores that improved by ≥ 0.05 points after surgery were Coping (0.09 points), Mental Health (0.06 points) and Relationships (0.05 points), which contribute to the Psychosocial super dimension. With regard to the Physical super dimension, Independent Living and Pain both improved 0.06 points and Senses showed a smaller improvement of 0.02 points (Table 3).

As mentioned previously, the cohort's HRQoL before surgery was substantially lower in comparison to population norms (Table 3; Fig. 2a, b). Individual dimensional scores improved 3 months postoperatively, but did not substantially approach Australian population norms, with the exception of two dimensions: Happiness and Coping (Table 3; Fig. 2a). The Psychosocial and Physical super dimensions' scores, while improved, were still substantially lower than the Australian general population norm at − 0.13 and − 0.27 points, respectively. The Physical super-dimension score was driven by the Pain dimension scoring 0.24 points less than the general population norm. Independent Living and Relationships also revealed large differences, scoring − 0.19 and − 0.13 points from the general population norm. Similarly, Mental Health/Self-worth and Senses also revealed scores of 0.09/0.09 and 0.08 less than their Australian general population norm equivalents, respectively. In contrast, the individual dimensions of Happiness and Coping approached both the general and 45–54-year age group population norms (Table 3; Fig. 2a, b).

4 Discussion

Our study is important because it is the first study to investigate the relative discriminatory power using dimensional comparisons of all 13 individual dimensions of the EQ-5D-5L and AQoL-8D for patients who endured multiyear wait times in a public health system and then underwent bariatric surgery.

As an important and emerging subgroup of bariatric surgery patients, our cohort also delivered an important and novel opportunity to provide clinicians with a better understanding of the 3-month postoperative impact of bariatric surgery on long-term waitlisted patients' complex physical and psychosocial domains of health.

4.1 A Head-to-Head Comparison of the EQ-5D-5L and AQoL-8D Revisited

In support of our findings from our previously published cross-sectional head-to-head comparison of privately treated patients who received bariatric surgery many years

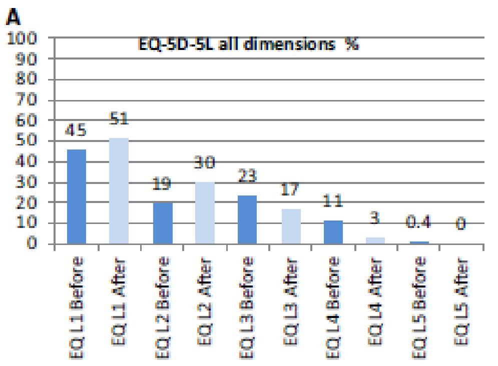
Fig. 1 **a** Distribution of participants' responses (%) for levels (L) 1–5 for all dimensions of EQ-5D-5L and AQoL-8D before surgery and 3 months after surgery. **b** Distribution of participants' responses (%) for Levels (L) 1–5 for the combined physical dimensions of EQ-5D-5L (Usual Activities, Self-care, Mobility, Pain) and AQoL-8D (Independent Living, Senses, Pain) before surgery and 3 months after surgery. **c** Distribution of participants' responses (%) for Levels (L) 1–5 for the combined psychosocial dimensions of EQ-5D-5L (Anxiety/Depression) and AQoL-8D (Coping, Mental Health, Happiness, Relationships, Self-worth) before surgery and 3 months after surgery

previously [9], this current longitudinal study revealed that the AQoL-8D preferentially captured and assessed the physical and psychosocial HRQoL for our cohort of long-term waitlisted patients who subsequently underwent bariatric surgery, even 3 months after their surgery.

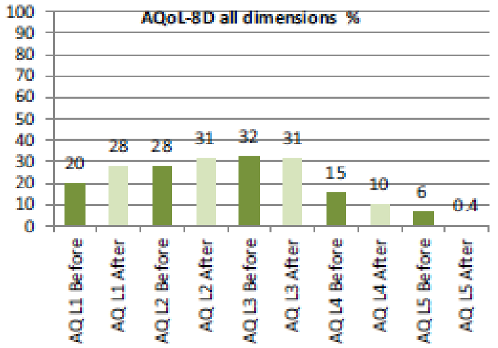
Amongst other direct comparisons of the discriminatory power of the two instruments, our earlier head-to-head study's comparison of the patient-reported distribution of the levels of response compared three (total six) individual comparable dimensions of both instruments (EQ-5D-5L: Anxiety/Depression, Self-care, Pain/Discomfort; AQoL-8D: Mental Health, Independent Living, Pain) [9]. In contrast, this current paper's head-to-head comparison conducted a longitudinal investigation for a study population of long-term publicly waitlisted bariatric surgery patients who underwent bariatric surgery as a targeted government policy decision to reduce waiting lists. Compared with our earlier study's examination of six individual dimensions, we investigated the patient-reported distributions of responses for the dimensional comparisons of all 13 individual dimensions of health for both instruments. Consequently, this study included an additional four (of the five) psychosocial domains of health for the AQoL-8D's classification system.

This current study particularly highlighted the depth and breadth of the AQoL-8D's classification system as compared to the EQ-5D-5L. Table 2 and Appendix 1 (see the ESM), coupled with schematic representations (Fig. 1a–c) of the dimensional comparisons, revealed that the AQoL-8D assessed and captured HRQoL across the broad classification system and through the levels (1 to 4–6) (there were no reported responses for level 6 for the AQoL-8D) given the relative dispersion of participants' responses away from perfect health. This is particularly highlighted with many of the responses for the EQ-5D-5L at level 1 (perfect health/ceiling effect) and level 2, compared to the AQoL-8D only recording just over half of the responses at levels 1 and 2. These findings support the superior discriminant sensitivity of the AQOOL-8D across the individual dimensions of physical and psychosocial health for the study population and as assessed in our previously published work [9].

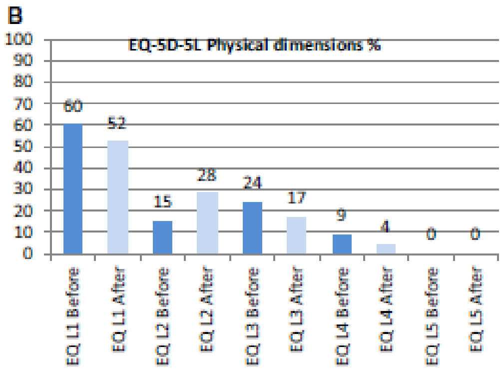
Appendix 5A: Publication of “An exploratory study: a head-to-head comparison of the EQ-5D-5L & AQoL-8D for long-term publicly waitlisted bariatric surgery patients before & 3 months after bariatric surgery”.



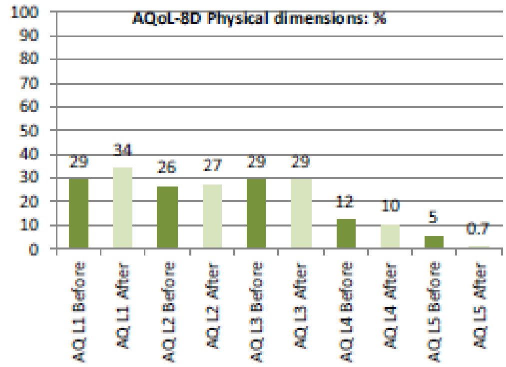
EQ-5D-5L five individual dimensions: Usual Activities, Self-care, Mobility, Pain and Anxiety/Depression.



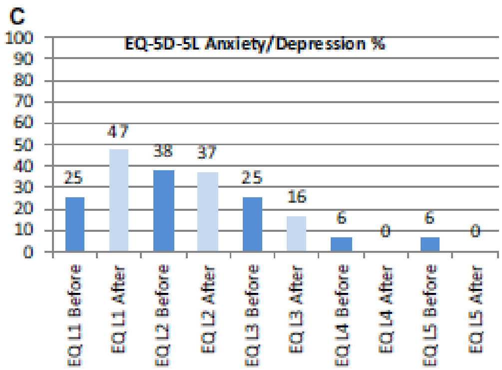
AQoL-8D eight individual dimensions: Independent Living, Senses, Pain, Happiness, Coping, Relationships, Self-worth, Mental Health.



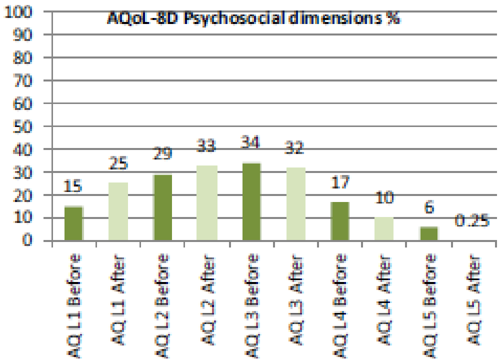
EQ-5D-5L four physical dimensions: Usual Activities, Self-care, Mobility, and Pain.



AQoL-8D three physical dimensions: Independent Living, Senses, Pain.



EQ-5D-5L one psychosocial dimension: Anxiety/Depression.



AQoL-8D five psycho-social dimensions: Happiness, Coping, Relationships, Self-worth, Mental Health.

Adis

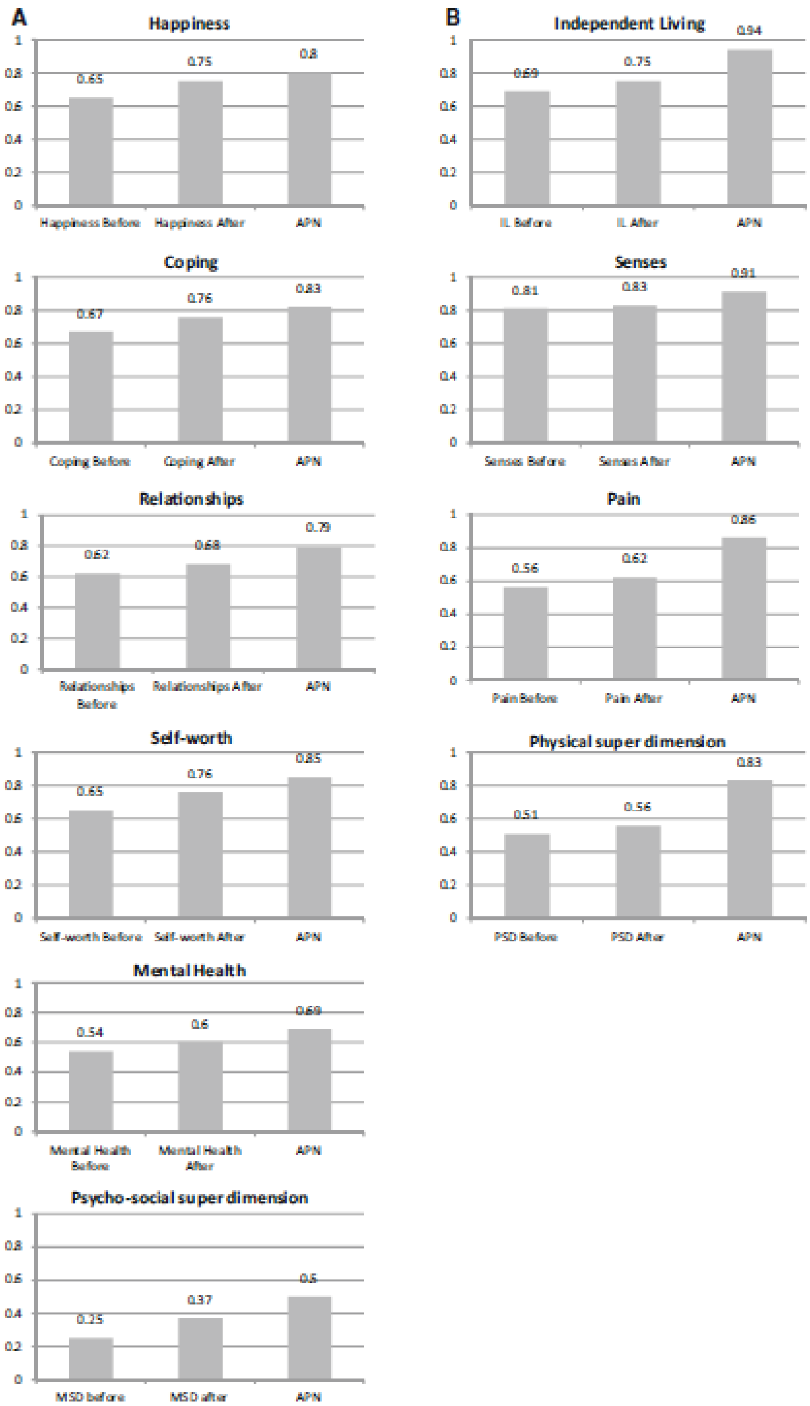


Fig. 2 **a** Comparison of before surgery and 3 months after bariatric surgery AQoL-8D scores and Australian Population norms (APN) for the individual psychosocial dimensions (Happiness, Coping, Relationships, Self-worth, Mental Health) and the Psychosocial super dimension. **b** Comparison of before surgery and 3 months after bariatric surgery AQoL-8D scores and Australian Population norms (APN) for the individual physical dimensions (Independent Living, Senses, Pain) and the Physical super dimension

This study's dimensional comparisons also found the individual dimension that revealed the most similar distribution for both instruments was Pain/Discomfort (EQ-5D-5L) and Pain (AQoL-8D). Therefore, our study's results suggest that both instruments were sensitive to the individual health domain of pain for the study population. Nevertheless, the AQoL-8D provided evidence of change in other domains of health that could be affected by pain, such as sleep, which impacts the Mental Health dimension.

Another key finding of our current study was that the pre- and postoperative summary utility valuations for the EQ-5D-5L were substantially higher (and indeed approached general population norms after surgery) than the summary utility valuations of the AQoL-8D. The AQoL-8D's relatively low preoperative and 3-month postoperative summary utility valuation revealed two important findings: first, the instrument's superior discriminant sensitivity relative to the EQ-5D-5L for the study population due to the AQoL-8D's ability to preferentially capture domains of health that are relevant for the study population; and second, the substantially lower (particularly preoperative) HRQoL for the long-term publicly waitlisted bariatric surgery patients. These findings also accord with evidence that suggests in practice all MAUIs which purport to measure utility give numerical values that differ significantly [12, 41].

4.2 Utility Valuations

Another key finding of our current study was that change in global utility valuations from before to 3 months after bariatric surgery exceeded the established minimal important differences for both instruments, and for the EQ-VAS. The instruments' summary utility valuations highlighted these long-term waitlisted bariatric surgery patients' considerably diminished physical and psychosocial health status before surgery, and the postoperative summary utility valuations revealed a clinical short-term improvement within the 3-month timeframe. Nevertheless, as discussed previously, compared to the EQ-5D-5L, the AQoL-8D revealed substantially lower pre- and postoperative utility valuations that did not approach population norms.

In particular, this study highlighted the substantially diminished preoperative AQoL-8D utility valuation for our study population. To provide a comparative perspective of the severity of our study population's diminished health state, a recent investigation that used data from a multinational (Australia, Canada, Germany, Norway, the UK and USA) cross-sectional survey found that for composite study populations of people with cancer or heart disease, the AQoL-8D mean (SD) utility valuation for cancer was 0.655 (0.22), and for heart disease, it was 0.667 (0.23) [48]. Therefore, our current study's findings particularly revealed that the preoperative AQoL-8D utility valuation for our cohort of severely obese long-term waitlisted patients was over 0.15 utility points less than that for a study population with cancer or heart disease. In other words, people who languish for long periods on the public waiting list can endure the same substantially diminished HRQoL status as someone with metastatic cancer or prolonged heart disease.

As an independent measure of HRQoL, there is emerging literature that suggests that utility valuations could be independent predictors of health outcomes. A study that investigated the predictive qualities of utility valuations derived from the EQ-5D in patients with diabetes found that they were useful in predicting for health events, including cardiovascular events (e.g. stroke, hospitalisation for angina), other major diabetes-related complications (e.g. heart failure, amputation, renal dialysis and lower extremity ulcer) and death from any other cause [21]. Bariatric surgery patients carry complex physical and psychosocial comorbidity loads, and the assessment of utility valuations in routine clinical care could provide a better understanding of this complexity at an individual patient level, informing preoperative and ongoing postoperative care. Prediction is more likely to be accurate when the instrument used for prediction takes account of the full range of the complex physical and psychosocial problems associated with the problem. Our study's findings suggest that the AQoL-8D is more likely to provide correct prediction than the EQ-5D-5L.

4.3 AQoL-8D's Individual and Super-Dimension Scores

Another key finding of our current study was the substantially lower AQoL-8D dimensional scores before surgery and improvements in these dimensional levels after surgery. Happiness and Coping improved the most after surgery and indeed approached population norms. Additionally, Self-worth also revealed a substantial change. All other individual dimensions improved, but did not substantially approach population norms. Recent evidence has found that body weight is only one contributing factor to the complex physical and psychosocial HRQoL needs of bariatric surgery patients [8].

4.4 Integrating Patient-Reported Outcomes in Clinical Practice

The International Society for Quality of Life Research has developed a clinical users guide to encourage the routine collection of PROs which "are rarely collected in routine clinical practice" [49]. Recent evidence has also found that integrating PROs in clinical practice has the potential to enhance patient-centred care. Within this broader and evolving context of patient-centredness in clinical care, our exploratory study highlighted the clinical relevance of MAUI analyses for long-term waitlisted patients who subsequently undergo bariatric surgery.

This study found that psychosocial health drove a relatively lower utility valuation for the AQoL-8D, despite clinical improvements. We suggest that bariatric clinicians could also further investigate and subsequently integrate and implement utility valuation's predictive qualities, and individual and super-dimension scores to further enhance patient-centred clinical care. Further studies could assess the feasibility of adopting a MAUI that preferentially captures and assesses physical and psychosocial HRQoL into the routine clinical assessment of these patients. We previously identified in our earlier published work that the AQoL-8D preferentially captured physical and psychosocial health for patients who had undergone bariatric surgery (in the longer term) [9], a position reinforced by our current analysis. Through MAUI analyses, our current study established clinically significant changes in psychosocial health (albeit from a relatively low baseline to post-surgical dimensional scores that were still relatively low) that warrant additional attention after surgery to improve overall postoperative health. Additionally, our current study's dimensional comparisons highlighted the EQ-5D-5L's relative insensitivity in distinguishing between health states close to full (or perfect) health for long-term waitlisted patients who had very recently undergone bariatric surgery.

4.5 Limitations

There are limitations to our study. The first limitation is small sample size. Nevertheless, our study was exploratory and we were provided with a novel opportunity to recruit participants from the long-term waitlisted patients subsequently fast-tracked for bariatric surgery through a government policy decision to reduce waiting lists. Our exploratory study of long-term waitlisted patients should inform larger confirmatory studies to test the validity of the EQ-5D-5L and AQoL-8D, and the short-term health impacts for long-term waitlisted patients. Nevertheless, we also acknowledge that a substantial commitment would need to be made at the public policy level to recruit a similar cohort of long-waiting patients. Other MAUIs such as the SF-6D could also be considered for larger confirmatory studies. The second limitation is that all participants were operated on by the same surgeon in the same hospital. This could affect the generalisability of our results if scaled up to all bariatric surgery patients. On the other hand, this circumstance could also be a strength given the homogenous nature of the sample.

The third limitation is that there is no control arm in the study. The observational nature of our study did not enable the recruitment of a control arm to elicit utility valuations; however, the key objective of this study was to compare the two MAUI. The final limitation is that the sample is at risk of participant selection bias, which could also affect the generalisability of our results.

A relative strength of our study is the high overall response rate of 74% to the questionnaires across the two time points.

The limitations of our study concur with our complementary study of the same cohort [11].

5 Conclusions

Within the small sample limitations of our exploratory study and to address the key objective of our study, which was a head-to-head comparison of the instruments, compared to the EQ-5D-5L, the AQoL-8D preferentially captured the complex physical and psychosocial short-term health changes for long-term publicly waitlisted patients who very recently underwent bariatric surgery. Importantly, researchers should understand a MAUIs descriptive/classification system and the innate sensitivities of the MAUI in regard to the particular study population, in this case long-term waitlisted patients who then undergo bariatric surgery. We recommend the AQoL-8D as a preferred MAUI over the EQ-5D-5L for bariatric surgery patients, given their complex physical and psychosocial needs.

In regard to our secondary objectives, utility valuations and dimensional scores (AQoL-8D only) revealed substantially lower health status for long-term waitlisted patients both before and after surgery, but with clinical short-term HRQoL improvements even 3 months after surgery. AQoL-8D preoperative utility valuation particularly revealed our study population's HRQoL was substantially lower than that of people with cancer or heart disease.

Dimensional comparisons, utility valuations, and individual and super-dimension scores could provide the clinician with both individual patient and cohort valuations that could lead to improved patient-centred care by identifying health domains requiring additional attention.

Routine integration of comprehensive MAUI analyses could provide clinicians with additional and independent assessments and predictors of HRQoL and in turn, enhance patient-centred care.

Data Availability Statement The dataset used for this study contains the following: the participant-reported responses to the EQ-5D-

Appendix 5A: Publication of "An exploratory study: a head-to-head comparison of the EQ-5D-5L & AQoL-8D for long-term publicly waitlisted bariatric surgery patients before & 3 months after bariatric surgery".

5L and the AQoL-8D MAUIs' questionnaires; the individual utility valuations (both instruments) and utility scores (AQoL-8D only) that were generated with the instruments' specific algorithm; the participant-reported EQ-VAS scores; and participants' socio-demographic and clinical data. The corresponding author will provide a de-identified dataset upon reasonable request for all or part of the data.

Author Contributions Julie Campbell contributed to study design, data collection, data verification and analysis, manuscript preparation, and final approval. Martin Hensher contributed to study design, manuscript review and final approval. Amanda Neil contributed to study design, manuscript review and final approval. Alison Venn contributed to study design, manuscript review and final approval. Petr Otahal contributed to the data analysis, manuscript review and final approval. Stephen Wilkinson contributed to study design, manuscript review and final approval. Andrew Palmer contributed to study design, data verification and analysis, manuscript review and final approval.

Compliance with Ethical Standards

The University of Tasmania's Health and Medical Human Research Ethics Committee (HMHREC) approved this study, and informed consent was obtained from all participants in accordance with the HMHREC's guidelines. This study was performed in accordance with the ethical standards of the Declaration of Helsinki.

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Conflict of interest The authors, Julie Campbell, Martin Hensher, Amanda Neil, Alison Venn, Petr Otahal, Stephen Wilkinson and Andrew Palmer, declare they have no conflict of interest.

Informed Consent Informed consent was obtained from all individual participants included in the study.

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Chapter 6: A qualitative investigation of the health economic impacts of bariatric surgery for obesity, and implications for improved practice in health economics.

Preface

Chapter 6 presents a qualitative health economics study to investigate the experiences of people waiting for, or who had received bariatric surgery.

Chapters 6 and 7 harnessed the advantages of qualitative research methods to identify and contextualise crucial costs and consequences of bariatric surgery that have typically been omitted, or not provided with sufficient priority in the health economic investigation and reporting of bariatric surgery.

The inspiration for the method of this qualitative study was partly generated from a conceptual synthesis of my PhD research's earlier studies and partly from a broader review of the published literature during my PhD research. In regard to the earlier studies of this thesis, Chapter 2's published systematic review identified the limited scope of costs and consequences for most health economic evaluation and reporting of bariatric surgery. The review recommended a more comprehensive investigation and reporting of health economic outcomes of bariatric surgery to identify aspects of the bariatric surgery patient's journey that reached well beyond the primary surgery's direct medical costs. Additionally, published Chapters 3, 4 and 5 established that psychosocial health is a vital consideration for people who are waiting for and then undergo bariatric surgery.

In regard to a broader review of the literature during my PhD research, I have found that over the past decade there has been a call for health economists to effectively integrate combinations of qualitative and quantitative methods into their research toolkit to enrich their research methodologies and therefore improve their practice in health economic study design, data gathering and analysis, reporting and ultimately research translation. Chapter 6 is consistent with this call for health economists to use qualitative methods in their research. In summary, this study employed qualitative research methods to broaden the evaluative space for the economic evaluation of bariatric surgery. The study achieved its objectives by frequent comparison of emergent thematic categories of the qualitative data (focus groups n=10; n=49 participants) with the pre-existing economic theories of emotional capital, economic perspective, and externalities.

The study identified that emotional capital is a key consideration and that some patients experienced financial hardship to access their surgery. This finding particularly consolidates the findings of Chapters 3, 4 and 5 of this thesis that identified that psychosocial health is an important consideration for people waiting for or who undergo bariatric surgery. It also follows the recommendations of Chapter 2.

This study was published in the highly regarded international health economics journal *Health Economics*. Please note that the Reference and Abstract style of this paper reflects the journal's style.

Impact factor: 2.3

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The published article found at the end of this chapter has been removed for copyright reasons.

Summary

Obesity is an economic problem. Bariatric surgery is cost-effective for severe and resistant obesity. Most economic evaluations of bariatric surgery use administrative data sources and narrowly-defined direct medical costs in their quantitative analyses. Increased prevalence of severe obesity and resource-constrained healthcare budgets means demand far outstrips supply for bariatric surgery. In turn, additional allocation of healthcare resources to bariatric surgery (particularly public) could be further motivated by new and convincing health economic evidence that supports the provision of bariatric surgery. We postulated that qualitative research methods would elicit important health economic dimensions of bariatric surgery that would typically be omitted from the current economic evaluation framework, nor be reported and therefore not considered by policy-makers with sufficient priority. We listened to patients: focus group data was analysed thematically with software assistance. Key themes were identified inductively through a dialogue between the qualitative data and pre-existing economic theory (perspective; externalities; emotional capital). We identified the concept of emotional capital where participants described life-changing desires to be productive and participate in their communities postoperatively. After self-funding bariatric surgery, some participants experienced financial distress. To improve health economic practice, we recommend a mixed-methods approach to the economic evaluation of bariatric surgery. This could be operationalised within the current framework in helath economic model conceptualisation and construction, through to the separate reporting of qualitative results to supplement quantitative analysis.

6.1 Introduction

6.1.1 Obesity and bariatric surgery

(i) The health and economic burden of obesity

Obesity is not just a public health problem, it is an economic problem (Ruhm, 2012, Cawley and Meyerhoefer, 2012, Wang et al., 2011, Cawley, 2015, Cawley, 2011, Lehnert et al., 2013, Gortmaker et al., 2011).

Overweight and obesity are defined by the World Health Organization (WHO) as '*abnormal or excessive fat accumulation that may impair health'* (WHO, October 2017). For adults, the WHO defines overweight and obesity as overweight is a body mass index (BMI) ≥ 25 kg/m²; and obesity is a BMI ≥ 30 kg/m² (WHO, October 2017). Obesity is further categorised into three classes: Class 1 obesity (obesity) is defined as BMI 30.0 – 34.9 kg/m²; Class 2 obesity (severe obesity (Cawley, 2015)) is defined as BMI 35.0 – 39.9 kg/m²; and Class 3 obesity is defined as BMI ≥ 40.0 kg/m² (World Health Organisation, 2016, Keating et al., 2015). Recent clinical literature also describes a fourth class of obesity that is categorised as 'super-obesity' defined as a BMI of ≥ 50.0 kg/m² (Gould et al., 2006, Peterson et al., 2017).

The current rates of obesity have been described as epidemic and severe obesity is increasing more rapidly than obesity (WHO, October 2017, Bray et al., 2017, Cawley, 2015). Nearly two-thirds (63.4%) of Australian adults are overweight or obese, with Tasmania recording the highest prevalence of the Australian States and Territories (67.5%) and the prevalence trends are increased in areas of socio-economic disadvantage (AIHW, 2017, Huse et al., 2017, Keating et al., 2015).

The economic burden of the obesity epidemic and its associated comorbidities places undue stress on healthcare systems (Withrow and Alter, 2011, Fallah-Fini et al., 2017, Cawley, 2015, Meyerhoefer and Cawley, 2016). People with obesity have medical care costs approximately 30% greater than their normal weight peers (Withrow and Alter, 2011). Additionally, medical care costs rise exponentially in the range of Class 2 and Class 3 obesity (BMI $\geq$35 kg/m^2) (Cawley et al., 2015). The most recent scholarly estimate of the total annual direct cost of overweight and obesity in Australia was estimated to be 21 billion Australian dollars in 2005 and this estimate was substantially higher than previous estimates (Colagiuri et al., 2010).

The economic burden of the obesity epidemic also extends well beyond the healthcare sector into societal domains including work productivity (Neovius et al., 2008, Wagner et al., 2007, Puhl, 2011, Lehnert et al., 2013, Goettler et al., 2017), and personal and family impacts arising from discrimination and stigmatisation of the overweight and obese both individually and collectively, poorer relationships and social engagement (Temple Newhook et al., 2013, Cawley, 2011). Some studies suggest that the costs of lost productivity due to obesity are several times larger than medical care costs (Wagner et al., 2007, Finkelstein et al., 2011).

(ii) Bariatric surgery as a treatment option for obesity

Bariatric (metabolic; weight loss) surgery is considered the most clinically efficacious treatment option for intractable severe and morbid obesity and bariatric surgery is increasing in prevalence (Buchwald and Oien, 2009, Buchwald and Oien, 2013, Angrisani et al., 2015a). Bariatric surgery results in greater weight loss and improvement in obesity-related comorbidities when compared with non-surgical intervention, regardless of the type of bariatric surgical procedure used (Colquitt et al., 2014, Angrisani et al., 2015b, Celio and Pories, 2016). Generally, bariatric surgery is recommended for people with resistant Class 3 obesity or resistant Class 2 obesity with obesity-related comorbidity (National Health and Medical Research Council, 2013, National Heart Lung and Blood Institute. United States Department of Health and Human Services, 1998, National Institute for Health and Care Excellence, 2014).

Demand for bariatric surgery far outstrips the supply of bariatric surgery places, particularly in public healthcare systems (Padwal et al., 2014, Gregory et al., 2013, Sharman et al., 2017, Campbell et al., 2016a, Campbell et al., 2017) Based on eligibility criteria, a recent Australian study determined that the potential demand for publicly- and privately-funded bariatric surgery in Australia was 882,441 adults aged between 18-65 years, with 45.8% of these potential bariatric surgery candidates having no private health insurance (Sharman et al., 2017). A recent Australian Institute of Health and Welfare (AIHW) study regarding weight loss surgery reported that in 2014–15, there were more than 22,700 weight loss surgery separations in Australia, most of which involved a primary procedure (79.4%) (AIHW, 2017). The majority of these bariatric surgery separations (88.0% or 20,000 separations) occurred in private hospitals (AIHW, 2017). Long-term publicly waitlisted bariatric surgery patients have recorded substantially diminished health-related quality of life (Campbell et al, 2017).

Constrained public sector budgets contribute to the incapacity of the Australian public health system to address the problems of severe obesity increasing more rapidly than obesity (Campbell et al., 2016a, Willis et al., 2016). The problem of demand for bariatric surgery far outstripping supply, and constrained public sector budgets is reflected internationally (Owen-Smith et al., 2013, Gill et al., 2014, Gagner, 2017, Hall, 2015, Campbell et al., 2017).

Economic evaluation of bariatric surgery generally finds the intervention to be cost-effective for people with severe obesity compared to non-surgical interventions, and possibly cost-saving as an intervention for severely obese people with type 2 diabetes (Borisenko et al., 2015, Campbell et al., 2016a). Nevertheless, our recent comprehensive systematic review of the health economic reporting of bariatric surgery that included 77 heterogeneous partial and full health economic evaluations found that most of the included studies were informed by administrative quantitative data and analyses, a narrow payer perspective rather than a broader societal perspective, and that out-of-pocket costs and productivity gains or losses were largely ignored (Campbell et al., 2016a). In turn, our review called for a more comprehensive investigation and reporting of the health economic outcomes of bariatric surgery to identify aspects of the bariatric surgery patient's journey that reached well beyond the primary surgery's direct medical costs (Campbell et al., 2016a).

6.1.2 Pre-existing theories: emotional capital, economic perspective and externalities

The pre-existing economic theories of emotional capital, perspective and externalities were adopted to inform the theory building of our qualitative study that investigated bariatric surgery patients' experiences whilst waiting for (mean (range) years 5 (2-7)), or following their bariatric surgery (mean (range) years 6 (0-31)). These concepts are explored below.

An important economic school of thought advocates that there is no behaviour that is not interpretable as economic (Becker 1962; Becker 2013). In turn, the concept of emotional capital was introduced by Gendron (2004) defined as '… the set of resources (emotional competencies) that inhere to the person useful for his or her cognitive, personal, social and economic development'. Emotional capital is vital for a person's well-being and achievement in life, and crucial for an organisation's success and survival: emotional capital shapes and conditions a person's entire life (Gendron 2004; Gendron 2007). It has been postulated that emotional capital is a 'booster capital': a capital which potentiates or energises the human, social and cultural capitals. Additionally, emotional capital is critical to enable human capital formation, accumulation, and, its optimal exploitation for individuals (Gendron, 2004, Andrade, 2015). Emotional capital should be considered as a 'capital', a real asset in which people, institutions and the society should invest, as it has major returns for individuals (to allow well-being and sustainable personal development) and for society (social cohesion) for (individual and social) life (Gendron, 2007).

Health economic evaluation provides healthcare policy-makers and planners with analyses to underpin decisions about committing scarce healthcare resources to one use instead of another. They require costs and consequences be *identified*, measured valued and compared between alternatives (Drummond et al., 2015). Very few economic evaluations of bariatric surgery employ a broader societal perspective, and out-of-pocket costs and productivity losses are largely ignored. (Campbell et al., 2016a).

External effects (externalities/spillovers) relate to the consequences of an action by one individual or group as they have an impact on others (Henderson, 2011, Culyer, 2014). The obesity epidemic imposes large external costs on society in the form of high medical costs and lower productivity which decrease social welfare: the costs of obesity extend to non-obese individuals (Cawley, 2015).

6.1.3 Qualitative research in health economics: improving health economics practice?

Over the past decade, there has been a call for health economists to effectively integrate combinations of qualitative and quantitative methods into their research toolkit to enrich their research methodologies and therefore improve their practice in health economic study design, data gathering and analyses, reporting, and ultimately research translation (Coast, 1999, Coast et al., 2004, Kelly et al., 2005, Smith et al., 2009, Obermann et al., 2013, Husbands et al., 2017). Additionally, health policy development, research, and management could benefit from more in-depth, textured descriptions of what actually happens in practice settings, healthcare markets, and patients' lives (Greenhalgh et al., 2016, Weiner et al., 2011). Nevertheless, recent evidence has found that only 9 % of published health economic research adopts qualitative research methods (Obermann et al., 2013, Weiner et al., 2011). Importantly, qualitative research methods could particularly identify *nuanced and policy-relevant arguments* regarding health economic impacts because major sources of relevant information, such as detailed knowledge of processes and context, goes untapped (Obermann et al., 2013).

For example, little has been done to highlight the benefits of using qualitative approaches to inform health economic model development: the validity and reliability of health economic models are constantly under scrutiny leading people to question the results (Husbands et al., 2017). It has been proposed that health economic modellers should consider the opportunities that qualitative methods provide to them. These opportunities include the application of qualitative techniques to model development processes in order to identify where problems are occurring and guidance is needed, and to contribute to the structural development of individual models (Husbands et al., 2017, van Voorn et al., 2016). In regard to health economic model conceptualisation (for health economic evaluation), patient involvement has been acknowledged as an important area requiring further research (Husbands et al., 2017, van Voorn et al., 2016). (Roberts et al., 2012). Furthermore, international guidelines regarding the conceptualisation of health economic models stated that consultations with patients may deepen understanding of the values and preferences relevant to the problem (ISPOR Taskforce 2) (Roberts et al., 2012).

There is also scope for augmenting the essential elements of economic evaluation with additional qualitative data to inform the context of the study (Kelly et al., 2005). Recently, qualitative methods have been used to inform trial design for a Health Technology Assessment with particular regard to patient narratives about the emotional, social and material environment (Morgan et al., 2015, Hoddinott et al., 2014).

There is also a call for health economists to implement mixed-methods policy-relevant research that is embedded in and derived from real-world policy settings (Obermann et al., 2013, Coast et al., 2004, Daniels et al., 2016). Mixed-methods policy-relevant and translatable research can be successfully generated through research partnerships between knowledge-users (e.g.

government) and academic researchers (Jose et al, 2016).

6.1.4 Qualitative research methods: improving our practice

The key objective of our study was to employ qualitative research methods to identify and/or inform the context of important health economic costs or consequences of bariatric surgery that would typically be omitted or not provided with sufficient priority within current economic evaluation frameworks. To achieve our main objective we listened to patients - we adopted qualitative research methods to gather and interpret patient-relevant data in an attempt to answer the following questions:

(1) Could qualitative research methods improve practice in health economic evaluation by supplementing quantitative methods to identify and put into context health economic costs and consequences of bariatric surgery that have typically been omitted or not fully understood within current economic evaluation frameworks?;

(2) Could qualitative research methods improve practice in the model conceptualisation and development phase of economic evaluation?;

(3) Could qualitative research methods improve practice in health economics by supplementing quantitative findings with qualitative findings in words and not numbers?; and

(4) Could the health economics findings from our qualitative study translate to the additional allocation of healthcare resources to bariatric surgery?

6.2 Materials and Methods

6.2.1 Study design

(i) Patient-relevant information

A study that has investigated patients as the ‘missing stakeholder group’ in the development of health economic modelling found that patients said "health care calculations are too narrow, excluding various second-order costs and benefits from treatments of chronic diseases simultaneously, and for whom cost-effectiveness analyses could be positive that are otherwise negative" (van Voorn et al., 2016). Additionally, stakeholder involvement is considered to be a critical aspect of good modelling practice and patients are important stakeholders who can add to health economic modelling (van Voorn et al., 2016). A focus-group style approach to include patient perspectives for model conceptualisation has been advocated within health economic modelling guidelines (Roberts et al., 2012).

Our qualitative health economics study conducted focus groups to gather qualitative data about bariatric surgery patients' experiences to elicit health economic impacts that would be omitted or not fully understood in the current economic evaluation framework for bariatric surgery.

Many economists share a certain conception that the process of scientific inquiry is the use of increasingly sophisticated mathematics to derive formal statements in mathematical language, and qualitative research that describes its research in words and not numbers is mostly ignored in this framework (Obermann et al., 2013). Our qualitative study also considers the value of describing the qualitative research findings in words and not numbers, in addition to the quantitative findings.

(ii) Participant recruitment and focus group structure

This study was conducted in Tasmania, an island state of Australia, which has a population of approximately 500,000 people with 67.5 % of adults classified as overweight or obese (AIHW, 2017).

Ethics' approvals for the study were obtained from our University's Social Sciences Human Research Ethics Committee. Detail regarding the focus group recruitment methodology is outlined in previous published work (Sharman et al., 2015). In summary, recruitment of focus group participants was achieved by advertising the study through local newspapers and radio. Letters were also sent to target groups of public and private bariatric surgery patients ensuring a mix of demographic and clinical characteristics. *A priori* we determined that significantly more females than males have bariatric surgery and most bariatric surgery is privately funded in Australia, for these reasons the groups were same sexed and separated by surgery funding type (Sharman et al, 2015). To ensure confidentiality, identifying details of participants were not shared between investigators. Table 1 provides an outline of focus group categories.

Table 1: Classification of focus groups (North and South of the State of Tasmania)

Focus groups (n=49 participants; (n=participants per group))	Structure
1 (5)	Females private health system greater than 3 years after bariatric surgery (South)
2 (7)	Females private system less than three years after bariatric surgery (North)
3 (6)	Females public system after bariatric surgery (South)
4 (2)	Females waitlisted for bariatric surgery (South)
5 (2)	Males waitlisted for bariatric surgery (South)
6 (7)	Males private system after bariatric surgery (South)
7 (4)	Females waitlisted for bariatric surgery (North)
8 (7)	Males public and private system after bariatric surgery (North)
9 (2)	Males waitlisted for bariatric surgery (North)
10 (7)	Females private health system greater than 3 years after bariatric surgery (South)

(iii) Economic data collection from focus groups

In regard to the focus groups' procedures, the pre-existing theories supported the initial development of health economics questions and prompts for the focus groups' discussion schedule. Meetings were convened with the qualitative research team (DE, MS), project lead (AV), and health economists (JC, AP, AN, MH) to discuss the gathering of health economic data from focus group discussions.

To elicit a broad range of health economic information the initial discussion schedule included a range of topics regarding costs and consequences before and after bariatric surgery. Two authors (JC and MS) discussed the progress of the ten focus groups as they were conducted (over a three month timeframe) and revised the health economic questions and prompts during these discussions in liaison with the broader research team. These questions and prompts guided the semi-structured focus group discussions to elicit the health economic data for thematic analysis.

Semi-structured focus group discussion techniques were used during the focus groups. Each focus group was no longer than 1.5 hours in duration, all were audio-recorded, transcribed verbatim and names were de-identified.

6.2.2 Data analysis

Thematic analysis underpinned by grounded theory (Strauss and Corbin, 1990, Strauss and Corbin, 1998, Liamputtong and Ezzy, 2005, Ezzy, 2013) informed the development of this study's sub and central themes through the process of open, axial and selective coding of the focus group transcripts. This thematic analysis was descriptive and interpretive and facilitated by use of software (QSRInternational, 2010). Table 2 provides an outline of the process of coding in thematic analysis.

More specifically, we adopted a sophisticated approach during grounded theory that mixed both inductive and deductive methods whereby the themes do not emerge from the data uninfluenced by pre-existing theory: there is an ongoing dialogue between data and theory in which emerging theories are repeatedly tested against the data (Ezzy, 2013). Our study used this process of frequent comparison of emergent thematic categories with the pre-existing economic theories of emotional capital, perspective and externalities.

During coding development, JC discussed the emergent themes with the other qualitative and health economic investigators. An audit trail was kept for the project that comprised of a journal of question development, focus group sessions and refinement of questions, all coding sessions, memos, reflective notes, emails, group meetings, and individual meetings with the first author.

Focus group participants' experiences are highlighted with quotations and longer verbatim quotes are italicised and indented.

Table 2: Coding in grounded theory and thematic analysis*

Open coding: • Explore the data. • Identify the units of analysis. • Code for meanings, feelings, actions. • Make metaphors for data. • Experiment with codes. • Compare and contrast events, actions and feelings. • Break codes into subcategories. • Integrate codes into more inclusive codes. • Identify the properties of codes. Axial coding: • Explore the codes. • Examine the relationships between codes. • Specify the conditions associated with a code. • Review data to confirm associations and new codes. • Compare codes with pre-existing theory. Selective coding: • Identify the core code or central story in the analysis. • Examine the relationship between the core code and other codes. • Compare coding scheme with pre-existing theory.

*Source: *Adopted from Qualitative Analysis: Practice and Innovation Douglas Ezzy (2013)*

Focus group participants' baseline socio-demographic and clinical data are presented descriptively as mean (standard deviation (SD)) for continuous variables and frequency (%) for categorical variables. Body mass index (BMI) was calculated as weight (kg)/[height (m)]^2. Percentage total weight lost (%TWL) was calculated as (lost weight / initial weight) *100 and percentage excess weight lost (%EWL) was calculated as (lost weight) / (initial weight – [25 * height (m)^2]) *100.

6.3 Results

6.3.1 Participant characteristics

Participant clinical and sociodemographic characteristics are provided in Table 3.

Table 3: Participants' clinical and socio-demographic characteristics

Characteristics (n=49)	**Participants who had undergone bariatric surgery (n=41)**	**Participants waitlisted for bariatric surgery (n=8)**
Age years		
Mean (SD)	55 (11)	54 (8)
Sex	Male (n=15, %)	(n=2, 25%)
(n=x, %)	Female (n=26, %)	(n=6, 75%)
Years since primary procedure		
Mean (SD)	6.3 (5.6)	NA
Median (IQR)	5.0 (3.0 – 9.0)	
Years on waiting list		
Mean (SD)	NA	5.3 (2.1)
Median (IQR)		6.0 (4.25 – 7.0)
BMI (kg/m²) maximum† (before surgery)		
Mean (SD)	45.9 (8.2)	NA
Median (IQR)	46.0 (40.0 – 49.0)	
BMI (kg/m²) current †† (at recruitment)		
Mean (SD)	34.1 (8.9)	41.0 (18.5)
Median (IQR)	32.0 (28.4 – 36.7)	43.8 (39.9 – 48.4)
Weight (kg)		
Maximum (before surgery)		
Mean (SD)	130.2 (27.7)	NA
Median (IQR)	130.0 (108.0 – 146.0)	
Current (at recruitment)		
Mean (SD)	96.4 (25.4)	128.2 (43.8)
Median (IQR)	92.0 (82.0 – 111.0)	113.5 (103.8 – 130.8)
% Total weight lost		
Mean (SD)	25.7 (12.5)	
Median (IQR)	24.3 (15.8 – 37.5)	NA
% Excess weight lost		
Mean (SD)	60.6 (28.8)	
Median (IQR)	63.5 (43.1 – 76.6)	
Number of participants		
(Maximum weight: before surgery)		
(n = x, %)		
BMI < 25 kg/m²	0	NA
BMI ≥ 25 – 29.9 kg/m²	0	
BMI ≥ 30 – 34.9 kg/m²	(1, 2%)	
BMI ≥ 35 – 39.9 kg/m²	(9, 22%)	
BMI ≥ 40 – 49.9 kg/m²	(21, 51%)	
BMI ≥ 50 kg/m² **	(10, 24%) **	
(at recruitment)		
(n = x, %)		
BMI < 25 kg/m²	(4, 10%)	0
BMI ≥ 25 – 29.9 kg/m²	(12, 29%)	0
BMI ≥ 30 – 34.9 kg/m²	(10, 24%)	0
BMI ≥ 35 – 39.9 kg/m²	(7, 17%)	(1, 14%)
BMI ≥ 40 – 49.9 kg/m²	(5, 12%)	(4, 57%)
BMI ≥ 50 kg/m² **	(3, 7%) **	(2, 29%)***
Highest level of education*	category 1 (11, 27%)	(2, 25%)
Category (%)	category 2 (6, 15%)	0
category 1 = year 10 or less; category 2 = year 11 and/or 12; category 3 = certificate, diploma or trade; category 4 = university.	category 3 (13, 32%) category 4 (11, 27%) *	(6, 75%) 0
LAGB (n=x, %)	(n=40, 98%)	NA
Secondary Procedure (n=x, %)	(n=6, 15%)	NA

*Highest level of education: category 1 = year 10 or less; category 2 = year 11 and/or 12; category 3 = certificate, diploma or trade; category 4 = university. SD = standard deviation, IQR = interquartile range. ** adds to 101% or 99% due to rounding, *** (n=7) one height not recorded. † self-reported weight. †† height and weight recorded before focus group session.

6.3.2 Thematic analysis of focus group data

The central theme that emerged from the interpretive analyses of our focus group data was that we identified important health economic outcomes regarding bariatric surgery that would have been omitted and/or not provided sufficient priority using the health economist's traditional quantitative toolkit, and within the current economic evaluation framework for bariatric surgery.

Key sub themes that were identified thematically are reported in detail below.

(i) Emotional costs and benefits: emotional capital

This study has revealed that participants' emotional reflections in the lead up to and after their bariatric surgery, and the transformation in most participants' preparedness to socially engage after surgery were vital health economic considerations. To illustrate, many participants described a complex socio-emotional personal journey from 'feeling judged' and 'stared at', and 'not wanting to leave the house' before bariatric surgery, to actively participating with their families, friends, work colleagues and broader society after their bariatric surgery. These findings support the emergence of the key theme of emotional capital as a capital and as a 'potentiator' for human capital. The emotional costs of being severely obese are substantial and influence morbidly obese bariatric surgery candidates' everyday private, participatory and broader social lives: their holistic well-being.

Before bariatric surgery many participants recalled 'feelings' and 'emotions' that drove them to social isolation, disengagement and self-persecution. One participant described an 'equation' of how overweight people were perceived by society 'equation: overweight, dumb, stupid'. Some participants expressed the point that 'it's all about how you feel, that's what it comes down to' and many participants echoed agreement during these discussions. For example, one participant described 'obsessive' negative thoughts about herself:

> '*I didn't have any… secondary [health] issues... My thoughts were quite obsessive; …Basically,… I couldn't continue to be the way I was… because of the way I felt about myself and the way that other people felt about me. … I had no secondary health issues to address – that wasn't the reason at all.'* (female, post-surgery private system).

Another participant also described the substantial impact that their obesity had on them socially and their preparedness to socially engage:

> *'You don't want to get up in the morning. You don't want to go and do what you should do. And actually I ate more, worrying about it.'*
>
> *But the emotions that you feel – and I'd become reclusive – which I'd always been an outgoing person, but I became that way. I didn't want to be in public. And I most definitely didn't want to eat in public because the size that I got, I'm thinking, "Everybody's looking at me." They're thinking, "Why is she even eating?* (female, post-surgery private system).

Focus group discussions revealed a deeper context and nuance regarding the wide-ranging *drivers* to the participants' social isolation were particularly dominant during the waiting list focus groups. Most of the study's waitlisted participants languished on the public waiting list for many years and they shared their entrenched feelings of frustration and what particularly drove them to situations where they 'can't go out of the house'. To illustrate, a male participant who had experienced a multiyear waiting time said:

> *'Your feelings are just shot 'cause you think, I can't go out of the house because every time I go out of the house I feel like crap. Um you get stared at all the time when you*

> *go through town. They just – just – it wrecks ya*.' (male, waiting list)

One participant who had been on the public waiting list for many years described the barriers to participating in paid employment. The participant mentioned that these barriers included things like not being able to 'get clothes for a start'. Interestingly, this participant did not attribute his inability to participate in paid employment because of his weight status, nevertheless, the issues he described 'medications, diabetes, incontinence' were clearly weight-related:

> '*I haven't worked since 2011.'*
>
> *[Interviewer] Okay. Because of your … weight?*
>
> *Yep. Well not necessarily because of the weight but because of everything .Um not being able to get clothes for a start. the medications, my incontinence, um the diabetes, and then the weight on top of it.'* (male, waiting list public system)

Nonetheless, there were a few people who said that they were seeking bariatric surgery for physical 'health benefits' only. These people did not describe or attribute their bariatric surgery journey to complexities about their socio-emotional status or the emotional 'feelings' that many of the focus group participants described. For example, one person said that:

> '*had a lap-band about six years ago and ah prior to that I had diabetes; type 2 I developed um high blood pressure. I had tried lots of weight things and got my weight down. I was sitting at 130-odd kilo'.* (male, post-surgery private system)

After bariatric surgery most participants described their increased self-esteem, self-worth and/or confidence by having 'more energy' and being 'social enough' to socially engage, or to now 'participate' in community volunteering or paid employment. Some participants said they ‘wanted to look good’ and that they were ‘being treated with more respect’. For example, one participant said she was trying not to be ‘vain’ about the fact that she could now ‘see her cheekbones and chin’ when she looked in the mirror and that she ‘avoided looking in the mirror’ before she underwent bariatric surgery. Table IV provides examples of relevant verbatim quotes from participants after they underwent bariatric surgery. Collectively, these verbatim quotes reveal increased self-esteem and confidence, participation and social engagement, and productivity. For example, one participant contrasted their before surgery experience of being on an invalid pension to their after surgery experience of wanting to seek part-time paid employment.

Table 4: Examples of verbatim quotes that support the theme of emotional capital after bariatric surgery.

Focus group	Full quotation
Females post-surgery private system less than three years	*It's given me all the confidence back in the world. I've had a few little issues with it to begin with, and had to go in and have a little bit more surgery. But just, I'm in – I'm back. That's really all I can say. So I would recommend it to absolutely everyone.*
	Well I'm actually looking now at the prospect of actually being able to go back and participate – contribute. You know and even the possibility of taking on some part-time work. So from becoming an invalid pension who could hardly shower myself, and all those things.
	But yeah health-wise, um I've got much more energy now than when I had my children. I can run around after my granddaughters now whereas I couldn't run around after my kids- *That was the basis behind me too. I thought, "Sooner or later I'm going to become a grandmother and I've got to be able to chase them"*
Females post-surgery public system	*Well one thing I have noticed is that when I was bigger, I'd just put on my big, floppy clothes and I – I've always worn make-up um because that's how I was brought up – that when you go out of the house you put make-up on. But I'd put my make-up on and that was the only time I'd look at myself in the mirror because I didn't like looking at myself. Um but as started losing weight I sort of – I tried not to be vain about it, but I'd keep looking at think, "Oh my God. I've got cheekbones. I have a chin.'*
Males waitlisted and then post-surgery.	*The change in my depression changing as well, 'cause it has helped quite a bit with my depression losing the weight. So it's got to the stage where you know my family have seen that change and they can see it's helped me quite a bit with my self-esteem um and even in my work um – I'm not working at the moment but when I was working up 'til June this year um my work colleagues even noticed the change. Um I mean they could see the weight coming off. They were going, "Oh I can't believe how quickly you're losing that weight," you know, and then they were saying, "You've become more alive, become more active," um you know, "and more interested in things compared to when you first started.'*
Males post-surgery public and private	*I had the operation two and a bit years ago now; um July 2012, I think it was. Um I – at the eighteenth month mark I reached my goal which was about 50 kilos down. Um and now I'm actually doing a personal trainer's thing so that I can help other people um start losing – losing and putting muscle mass on. So yeah. That's pretty much where I am at the moment.*
Females post-surgery private greater than three years	*'Definitely people treat you with more respect if you've got less weight. I wouldn't have been able to get things that I've got through – you know if I hadn't got it done. So in some ways it's been a really good thing for me. You know I met – I basically wouldn't have been social enough to meet anyone and get married. I was you know in my late-thirties before I met anyone because I just was like thinking, "Well, you know I didn't want to go out." I had this perception'* *'It's all how you feel. That's what it comes down to-*

(ii) Out-of-pocket costs

The potential range of out-of-pocket costs and the consequences of financial burden and distress (individually or within the household budget) are an important consideration for people who are undergoing bariatric surgery. Some people discussed partially or fully self-funding the primary surgical procedure by 'paying cold hard cash for the whole thing'. A couple of participants from lower-socio economic groups accessed the private system by either purchasing private insurance specifically for the primary surgical procedure where there were also substantial co-payments, or fully funding the procedure by accessing their superannuation: ‘so I took the money out of my super to have it done because I just felt so strongly about it’. To illustrate, one participant described herself as ‘poor’ and she highlighted the considerable financial burden of the private health insurance co-payment:

> *‘Well I had a three-and-a-half thousand dollar ... gap that I had to pay and being on a pension I just paid it off. We had a few battles over that but ah, “You can’t get blood from the stone,” as I told them so they just had to wait. And they did, I think it was about 18 months it took me to pay it off. but on a pension there’s not much you can do. Poor’s poor and that’s it.*’ (female, post-surgery private system).

Additionally, a couple of participants described the financial burden of fully self-funding the primary procedure:

> *‘I’d say eight [thousand dollars]…And it’s amazing how many do.*
>
> *[New Speaker] Eleven thousand.*
>
> *Yeah, and that hurts’* (female, post-surgery private system)

Some participants described their frustration about enduring multiyear waiting times on the public healthcare system waiting list. Consequently, a few participants decided to pay for private healthcare by either using their own funds for the primary surgical procedure and follow-up healthcare costs or taking up relatively expensive private health insurance (with concomitant ‘gap’ payments) to pay for the primary surgical procedure.

Participants also described the burden of small but relatively regular unexpected out-of-pocket costs. Some participants discussed the unexpected frequency of band adjustments (one participant mentioned six weekly adjustments) and concomitant out-of-pocket co-payments:

> *'The adjustment I think is 10 dollars; just the adjustment. And that's to cover – I think that's to cover the equipment that they use because I think most of its just thrown away'* (male, post-surgery private system).

> *'I'm out-of-pocket like 60 bucks [dollars] when I go- ...I have to pay like 170 and I get one-hundred-and-something back, but I'm out-of-pocket 50, 60 dollars when I go.'* (female, post-surgery private system).

Our study also found that body-contouring surgery to remove excess skin was acknowledged as a potentially important follow-up procedure for focus group participants. After rapid and continued weight loss, bariatric surgery patients are often left with heavy skin folds of redundant skin and contour irregularities and the resultant functional problems have raised concerns about effects on quality-of-life (Soldin et al., 2016). Several participants expressed a desire for body-contouring surgery in the future to remove excess skin, sometimes even years after the initial surgical procedure. Some participants indicated that they desired body-contouring procedures but that they could not 'afford' the procedure. One participant said that they paid for the cost of the body-contouring procedure(s) out-of-pocket:

> *It was almost as much as I originally paid for the – the first lap-band. So I'd be looking at around 10 grand [10 thousand dollars].'* (female, post-surgery private system)

(iii) Implications for improvement in practice

Bridging the gap between our qualitative results and the current economic evaluation framework for bariatric surgery could be achieved by creating a specific 'emotional capital' bolt-on item for the internationally prevalent multi-attribute utility instrument the EQ-5D and testing this against the AQoL-8D multi-attribute utility instrument that is preferentially sensitive for the bariatric surgery study population, or by developing a separate survey instrument for emotional capital. Additionally, the conceptualisation and construction phase of an individual health economic evaluation model could take into account the patient-relevant findings of emotional capital and out-of-pocket costs.

The operationalization of our key findings within the current economic evaluation framework for bariatric surgery are discussed in detail below.

6.4 Discussion

Our study is important because qualitative research methods enabled us to identify health economic impacts of bariatric surgery that typically have been excluded from existing health economic evaluations. Through a dialogue between the qualitative patient-relevant data and pre-existing economic theory, we identified and prioritised the concept of emotional capital as a ‘booster’ for human capital where participants described fundamental life-changing outcomes and desires to be productive and participate in their communities postoperatively. We also found that of the two-thirds of the focus group participants that accessed the private healthcare system for their surgery, some experienced substantial economic burden to do so. Another important finding was the identification of body-contouring surgery as an integral to the treatment journey, nonetheless prohibitively costly.

6.4.1 Emotional capital leading to participation and productivity

By listening to patients we found that emotional capital is paramount for the study population. Many participants described the way that they ‘felt’ and their ‘emotions’ about themselves as the most important drivers supporting the desire to undergo surgery, and/or the success of their bariatric surgery. Focus group participants described and put into context an overall positive outlook and coupled with their increased physical function enabled many participants to ‘leave the house’ and engage with society in a participatory, productive and meaningful way. Some people described a desire to participate or their participation in paid employment, others described wanting to volunteer in their communities and socially engage. These are important productive and participatory variables, whereby emotional capital is in fact boosting human capital: they should not be ignored or devalued by health economists in the health economic evaluation and reporting of bariatric surgery.

Recent evidence suggests that patient-centred care is increasingly important and relevant for informed healthcare decision-making (Basch et al., 2015). As the missing stakeholder group in the development of health economic models, patients have said that health care calculations are too narrow (van Voorn et al., 2016). Our qualitative health economic study revealed that bariatric surgery patients inherently embody multifaceted physical and psychosocial lived complexities that can only be fully captured, evaluated and explained by adopting the unique advantages of qualitative research methods. More specifically, our study showed that qualitative techniques enabled the innate complexity of these people's lives to emerge, to identify areas of difficulty and success in regard to their bariatric surgery both pre- and postoperatively that ultimately translated to health economic ramifications. For example, by exploring bariatric surgery patients' stories we showed that participation and productivity are key to the surgery's success and they are also key to the publicly waitlisted patients' frustration and plight. Our study's examination of emotional capital provided a deeper, nuanced and contextual understanding of the socio-emotional status of our study population. The participants' individual stories coupled with the exchange of their lived experiences provided new and highly relevant information about the 'how' and 'why' of psychosocial health status. This important information should be considered with sufficient priority in health economic evaluation and subsequent resource allocation decisions.

The following sections explore examples of how we could operationalise the study's key findings to improve the economic evaluation of bariatric surgery.

(i) The EQ-5D: an emotional capital bolt-on item?

Psychosocial health status has been increasingly identified as an important health-related quality-of-life outcome measure for morbidly obese patients who receive bariatric surgery (Herpertz et al., 2015, Campbell et al., 2017, Campbell et al., 2016b)). Most cost-utility analyses of bariatric surgery adopt the internationally prevalent EQ-5D multi-attribute utility instrument to assess the health-related quality-of-life impacts of the intervention however four of the five items of the EQ-5D focus on physical health (Campbell et al. 2016a). Our recent suite of studies revealed that the EQ-5D-5L, compared to the AQoL-8D, does not preferentially capture or assess the psychosocial health status for people who are waiting for or who have undergone bariatric surgery. The AQoL-8D multi-attribute utility instrument has instead been recommended due to the instrument's substantially broader descriptive/classification system concerning psychosocial health status (Campbell et al., 2016b, Campbell et al., 2017, Richardson et al., 2014). At the individual question level for the AQoL-8D (e.g. social isolation), our qualitative research provided an even deeper and contextual understanding of the socio-emotional drivers for many participants' inability to participate and socially engage, their social isolation before bariatric surgery.

Our qualitative study's interpretative analyses of participants' socio-emotional experiences further highlighted the fundamental inadequacy of the EQ-5D for the study population.

Emergent published literature has explored the concept of 'bolt-on' items to augment the EQ-5D's existing classification system that focuses on physical health (Devlin and Brooks, 2017, Yang et al., 2015). Some of this literature has cautioned against the development of bolt-on items because it could detract from 'the advantages of using a generic instrument' (Yang et al., 2015). A study that discussed the past present and future of the EQ-5D and the EuroQol group also stated that this approach could raise issues as follows:

> *'the EuroQol Group is also undertaking experiments on another approach to enhancing instrument performance in certain population sub-groups i.e. through the use of 'bolt-on' dimensions. In its simplest form this retains the core five dimensions, but adds one or more dimensions to capture aspects of health which may not be adequately captured by these dimensions. Some initial experiments with bolt-ons have been undertaken for vision, hearing, tiredness, psoriasis and sleep. At a descriptive level, the introduction of bolt-on dimensions can add to the richness of respondent profile data. However, this approach raises non-trivial issues, especially in connection with the consequences for health state valuations in the expanded instruments.'*

Our suite of published studies established that the EQ-5D-5L's descriptive system is inadequate for different subgroups of the bariatric surgery study population. (Campbell et al., 2016b, Campbell JA, 2017, Campbell et al., 2017). One of our studies also acknowledged that the use of bolt-on items may result in consequences for health state utility values including non-interchangeablity (Campbell et al., 2016b). We also established that, as a single multi-attribute utility instrument, the AQoL-8D captures the vast majority of domains considered crucial in the bariatric surgery study population (Campbell et al., 2016b).

Notwithstanding the caveats outlined above, we suggest that a bolt-on item for the concept of emotional capital could be explored for the EQ-5D-5L. It is vital that development of an emotional capital bolt-on item be tested against the AQoL-8D multi-attribute utility instrument that preferentially captures the complex physical and psychosocial health-related quality of life for the bariatric surgery patients when compared to the EQ-5D-5L.

We also make the vital point that our qualitative results provide a deeper and nuanced understanding of psychosocial health for the study population and the concept of meotional capital could also be reported separately in its qualitative form.

(ii) Qualitative methods to supplement quantitative methods: health economic modelling

Patients are key stakeholders in health economic modelling, yet their involvement is sparse at best (van Voorn et al., 2016). Arguments in favour of patient involvement in model development (and therefore model credibility) include the identification of relevant factors such as costs - patients have said that 'health care calculations are too narrow, excluding various second-order costs and benefits from treatments of chronic diseases simultaneously, and for whom cost-effectiveness analyses could be positive that are otherwise negative' (van Voorn et al., 2016). We recommend that the concept of emotional capital should be explored in the health economic model conceptualisation and construction phase of the health economic evaluation of bariatric surgery. In particular, participation and productivity could be explored – for example, does emotional capital lead to labour market productivity? Additionally, our qualitative findings could be reported separately in their qualitative form to supplement the quantitative results of an economic evaluation.

In summary, if emotional capital is understood within the current economic evaluation framework, emotional capital could be prioritised by healthcare policymakers and planners. The concept of emotional capital provides further context concerning the socio-emotional or psychosocial drivers for patients seeking bariatric surgery (including what drives patients to endure waitlist times and what happens during that time, the purchasing private insurance and self-funding), and the subsequent success of the bariatric surgery (ultimately translating into productivity). In other words, the success of bariatric surgery is not just about losing weight, it is about the complex psychosocial needs of these patients before and after their bariatric surgery.

6.4.2 Financial hardship and a broader perspective

Our study established that some participants who accessed the private healthcare system through self-funding the primary procedure experienced substantial financial burden to do so, and that regular unexpected (albeit small) out-of-pocket payments were prevalent.

The consequences of financial burden due to out-of-pocket expenditures for people who undergo bariatric surgery (and indeed other disease categories across different healthcare systems) are poorly understood (Timmons et al., 2013, Ubel et al., 2013, Gott et al., 2015, Wu et al., 2014, Aji et al., 2014, Campbell et al., 2016a). A recent study has found that financial distress is a key determinant of health (Meyer, 2017).

Previous work has found that there is much scope for augmenting the essential elements of economic evaluation with additional qualitative data to inform the context of the study (Kelly et al., 2005, Husbands et al., 2017, van Voorn et al., 2016). Additionally, from an individual study perspective, patient narratives have been used to inform a recent UK Health Technology Assessment about the emotional, social and material environments that informed the ‘push and pull’ of financial incentives to modify participants’ (pregnant and breastfeeding women that smoke) smoking behaviour (Hoddinott et al., 2014).

The conceptualisation and construction phase of a health economic model could, for example, take into consideration that patients who are experiencing financial distress are at a higher risk of seeking ongoing bariatric surgical care (such as complications and reoperations) in the public healthcare system. In regard to potential complications and reoperations, recent evidence has found that complications and/or reoperations can cost as much as the primary procedure itself, and that the estimated rates (particularly after secondary bariatric surgery) are higher than the usually reported risks (Campbell et al., 2016a, Kuzminov et al., 2016). In turn, some of these participants may allow their private health insurance to lapse if they experience even more financial hardship, increasing likelihood of future presentations for complications and reoperations through the public sector. Financial hardship could also be linked with emotional capital and this could be explored further in relation to financial distress as a key determinant of health.

Our study also found there was a general acknowledgement that body-contouring procedures (as an ongoing procedure) are an integral part of the patient's journey and these procedures are a consideration even for people publicly waitlisted for surgery. Our study established that out-of-pocket costs of body-contouring were considered to be prohibitive and comparable to the cost of the primary bariatric procedure.

Overall, our qualitative health economic study revealed some complex choices for policy-makers and funders. We showed that some patients experienced economic burden to fully or partially self-fund their primary surgery in the private healthcare system. Importantly, there are a range of additional or ongoing procedures and costs related to bariatric surgery after the primary procedure - not providing adequately for these costs through public coverage (or, indeed, in private health insurance benefit schedules) may simply push significant costs onto patients – who may quickly turn to the public sector by default if they are unable to finance them.

6.4.3 Qualitative research methods: improving health economics practice

Our study highlighted clear pathways regarding the practical implications of our key findings to improve our health economics practice in the economic evaluation of bariatric surgery from model conceptualisation and construction through to the separate reporting of qualitative findings. Qualitative research methods revealed the importance of emotional capital and out-of-pockets costs for bariatric surgery patients: qualitative methods should supplement quantitative methods to elicit nuanced and detailed analysis of the health economic impact of waiting for and/or undergoing bariatric surgery.

It has been suggested that the application of qualitative methods to the development of health economic models for bariatric surgery will enhance the credibility of the model. A focus group-style approach for model conceptualisation has been advocated within modelling guidelines, particularly for patient involvement as a key stakeholder group (Roberts et al., 2012).

Our qualitative study also highlighted the importance of a key finding of our previously published systematic review that recommended a broader societal perspective in the health economic evaluation and reporting of bariatric surgery, and the appropriate consideration of out-of-pocket costs, complications and reoperations and productivity gains or losses (Campbell et al., 2016a). Fully accounting for all such costs may impact not only on the affordability of bariatric surgery, but potentially on its cost-effectiveness. The important point here is that standard health economic evaluation should factor all of these known knowledge gaps/costs into their economic evaluation through the identification process at a minimum. Putting this into perspective, in practice – they do not. This paper has revealed and highlighted key costs and consequences that should be afforded sufficient priority and included in health economic reporting. More importantly, this paper has highlighted the consequences of not prioritising the inclusion of these costs and consequences in health economic reporting of bariatric surgery.

Overall, we suggest that the unique advantages of qualitative research methods in a mixed-methods setting can provide health economists with important information about key costs and benefits that would otherwise be overlooked, not fully understood and not afforded sufficient priority in the health economic evaluation of bariatric surgery. Furthermore, key questions of "sufficiency" versus "gold standard" care are visible here – for example, is body-contouring surgery really necessary, and if it is not, should it be provided at all in publicly-funded systems?

The dissemination of qualitative health policy research is the subject of concentrated debate in the contemporary scholarly literature (Daniels et al., 2016, Greenhalgh et al., 2016). Supporters of qualitative research argue that this research explores and explains the complex relations between the healthcare system and the outside world, such as the socio-political context in which healthcare is regulated, funded, and provided, and the ways in which clinicians and regulators interact with industry (Greenhalgh et al., 2016). Supporters also contend that the marginalisation of qualitative research in 'special interest journals' devalues the work relevant to health services, weakens understanding of the interface between qualitative and quantitative research and undermines the breadth and the quality of the analysis (Daniels et al., 2016).

We have provided our government partner with a contextualised understanding of the psychosocial health impacts of bariatric surgery. Our previously published quantitative analyses revealed that psychosocial health status is a crucial to the success of the surgery (Campbell et al., 2017). Importantly, our qualitative results provided a deeper understanding of the *how* and *why* psychosocial health status is important. In turn, our research has informed some of the future direction of our ongoing research program, and highlighted important policy gaps to our government partners.

We also acknowledge challenges must be overcome to enable the operationalisation of our key findings within the current economic evaluation framework for bariatric surgery. These challenges could include the lack of appropriate knowledge and skills in qualitative research, and the entrenched 'quantitative culture' within the health economics community. Nevertheless, there has been a growing advocacy for mixed-methods research in health economics, including Health Technology Assessment programs and Cochrane Collaborations

(Coast, 1999; Coast et al., 2004; Obermann et al., 2013; Husbands et al 2017 (Greenhalgh et al., 2016)), and our research has attempted to address this evidence gap for bariatric surgery.

Additionally, recent evidence of partnership arrangements between academics and policy-makers, that is knowledge-users and researchers, can be a powerful mechanism for improving the policy relevance of research (Jose et al., 2016). This study is part of a broader collaborative partnership arrangement between key government policy-makers and researchers. It is also a good example of the generation of policy-relevant qualitative research in health economics where interpretivist qualitative methodologies have been adopted to complement and enhance the quantitative component. We identified important and complex policy issues for the consideration of healthcare decision makers regarding the supply of bariatric surgery to meet ever increasing demand on the Australian healthcare system. We have revealed the how and why to complement the how much.

6.4.4 Strengths and Limitations

The key limitation of our study was that the scope of our investigation was restricted to focus group data. Follow-up in-depth interviews of key participants could further enrich our understanding of the key themes identified in our study.

There were several strengths to our study. First, the use of qualitative research methods to identify key knowledge gaps in regard to the health economic impacts of bariatric surgery. Second, the economic component of the focus group discussions were embedded and thus identified during discussions of the broader 'lived' experiences of participants. Third, we had a large sample size (n=49) for qualitative research, with diversity of participants' treatment modality (i.e. public/private/waitlisted), and socio-demographic characteristics. Finally the research team embodied a combination of knowledge and skills of experienced qualitative researchers and health economists from research and policy-making backgrounds to enable a multi-disciplinary investigation of the predominantly quantitative health economic research of bariatric surgery.

6.5 Conclusions

Qualitative methods can inform improved practice in the health economic analyses of bariatric surgery by eliciting health economic impacts of an intervention that would typically be excluded or not provided with sufficient priority in reporting to the healthcare decision maker.

Emotional capital is a key health economic consideration for people who are waiting for and/or undergo bariatric surgery and should be considered with sufficient priority by healthcare decision makers. The disproportionate level of financial burden endured by some individuals who undergo primary bariatric surgery privately should be investigated as a reason or in the light of their potential subsequent access of publicly funded healthcare.

To provide further supporting eviednece regarding the allocation of additional healthcare resources to bariatric surgery as a treatment for the increasing prevalence of severe and resistant obesity our key findings could be included in the conceptualisation and construction of a health economic model or reported as supplementary information to economic evaluation.

We suggest that the benefits derived from mixed-methods health economic research regarding bariatric surgery far outweigh the costs of including robust qualitative research methods within study design and subsequent reporting. Key policy decision-makers and ultimately patients and their carers would derive substantial benefits from health economic analyses and reporting that harnesses the unique advantages of qualitative techniques.

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Appendix 6A: A qualitative investigation of the health economic impacts of bariatric surgery for obesity, and implications for improved practice in health economics.

Chapter 7: A qualitative investigation of information asymmetry for obesity surgery: diversity of patient experiences in the information age and demand-induced supply.

Preface

Chapter 7 presents the second health economics study of this thesis that implemented qualitative research methods to investigate the experiences of people waiting for, or who had received bariatric surgery.

The inspiration for the method of this qualitative study was partly generated from a conceptual synthesis of my PhD research's earlier studies and partly from a broader review of the published literature (particularly health economic methodology) during my PhD research. In regard to the earlier studies of this thesis, Chapter 2's published systematic review identified the limited scope of costs and consequences for most health economic reporting of bariatric surgery and called for a more comprehensive investigation and reporting of health economic outcomes of bariatric surgery to identify aspects of the bariatric surgery patient's journey that reached well beyond the primary surgery's direct medical costs. Published Chapters 3, 4 and 5 established that psychosocial health is a vital consideration for people who are waiting for and who then undergo bariatric surgery; and Chapter 6 revealed that the concept of emotional capital is a key driver for the success of bariatric surgery.

In regard to my broader review of the published literature during my PhD research, Chapter 7 investigated the emergence of the concept of demand-induced supply in the information-age for people waiting for or who undergo bariatric surgery. Does demand-induce supply exist in the marketplace of bariatric surgery? Are bariatric surgery patients more information-savvy in the information-age? Chapter 7 is also consistent with a call for health economists to effectively integrate combinations of qualitative and quantitative methods into their research toolkit to enrich their research methodologies.

In the information age, patients may be more empowered in their negotiated relationship with healthcare providers, and information asymmetries may occur that place patients in a superior information position to healthcare professionals. Therefore, the main objective of this study was to employ qualitative research methods to investigate the concept of information asymmetry for bariatric surgery patients in the information age. The study achieved the objective by frequent comparison of emergent thematic categories of the qualitative data (focus groups n=10; n=49 participants) with the pre-existing economic theories of information asymmetry, the principal-agent relationship and demand-induced supply.

This study established that psychosocial or socio-emotional drivers informed the sources and types of information that were important to participants preoperatively. The study also found that information sources relevant to participants preoperatively (e.g. family and friends, and the Internet) were different postoperatively (surgeon, allied-health professionals e.g. psychologist). This study identified important information 'drivers', sources and types (including the quality and consistency of information), and the divergence of what information is 'important' to bariatric surgery patients in the pre- and postoperative periods.

This qualitative study revealed key considerations for the healthcare decision maker about bariatric surgery patients' information gathering and use. This qualitative health economics study recommended that high-quality and consistent information sources be targeted towards the psychosocial domains of health for bariatric surgery patients preoperatively and ongoing postoperatively. The study also recommended that appropriate healthcare information be provided to enable a smoother transition for the management of physical health impacts such as postoperative dehydration and electrolyte imbalance which can result in unexpected hospitalisation: smoother postoperative transition would likely translate to less burden on the healthcare dollar.

Please note that the Reference and Abstract style of this paper reflects the submitted journal's style. This chapter has been submitted to *PharmacoEconomics.*

Impact factor: 3.99

Campbell JA, Ezzy D, Hensher M, Neil A, Venn A, Sharman MJ, Wilkinson S and Palmer AJ. A qualitative investigation of information asymmetry for obesity surgery: diversity of patient experiences in the information age and demand-induced supply.

Summary

A key market failure in healthcare is information asymmetry between the consumer and supplier where the level of knowledge and expertise is weighted to the supply-side (physician/surgeon). In the information-age, bariatric surgery patients may be more empowered in their negotiated relationship with healthcare providers. Importantly, information that empowers the consumer potentially enables ‘demand-induced-supply’ (patients demanding and receiving care that their clinician would not otherwise have offered) and has implications for healthcare resource allocation to bariatric surgery. Our study used the pre-existing health economics theory of information asymmetry to inform qualitative inductive and deductive theory building about information drivers, sources and needs for bariatric surgery patients pre- and postoperatively. Ten semi-structured focus groups of people who were waitlisted or had undergone bariatric surgery were conducted (n=49). Thematic analyses were employed to analyse verbatim transcripts. We found a divergence between the pre- and postoperative information drivers. Psychosocial or socio-emotional drivers informed the sources and types of information that were important to participants preoperatively. We also found that information sources relevant to participants preoperatively (e.g. family and friends, and the Internet) were different postoperatively (surgeon, allied-health professionals e.g. psychologist). We recommend that high-quality and consistent patient information be more targeted towards the psychosocial domains of health preoperatively and ongoing postoperatively.

7.1 Introduction

7.1.1 Qualitative research in health economics

Our study adopted qualitative research methods to investigate information asymmetry in the market for obesity surgery, consistent with a call for health economists to effectively integrate combinations of qualitative and quantitative methods into their research toolkit to enrich their research methodologies (Coast et al., 2004, Coast, 1999, Obermann et al., 2013, Campbell JA, 2018). Importantly, it has been suggested that qualitative research methods could particularly identify nuanced and policy-relevant arguments in health economics and that major sources of relevant information in health economics' research goes untapped including the *meaningful* participation of patients in health economic model conceptualisation and development (Obermann et al., 2013, Campbell JA, 2018).

7.1.2 Obesity (bariatric) surgery

Obesity is a public health and economic problem (Cawley, 2011, Cawley, 2015, Cawley and Meyerhoefer, 2012, Gortmaker et al., 2011, Campbell et al., 2018, Campbell et al., 2016a). Obesity surgery (clinically described as bariatric or metabolic surgery) as a treatment intervention for obesity and related comorbidity has been increasing across developed and developing countries (Angrisani et al., 2015, Buchwald and Oien, 2013). Bariatric surgery is generally recommended for those with intractable class 2 obesity [body mass index (BMI) 35–39.9 kg/m^2] and obesity-related comorbidity (e.g. type 2 diabetes mellitus, cardiovascular disease or joint pain) or class 3 obesity (BMI $\geq$ 40 kg/ m^2) with or without obesity-related comorbidity (NHMRC, 2013).

Recent evidence has found that psychosocial health-related quality-of-life (HRQoL), including the concept of emotional capital, is a fundamental consideration for people awaiting or who have undergone bariatric surgery, and that weight status is only one factor contributing to these complex HRQoL outcomes for this study population (Burgmer et al., 2014, Herpertz et al., 2015, Campbell et al., 2016b, Sharman et al., 2016a, Campbell JA, 2018).

7.1.3 The information age: from Kenneth Arrow 1963 to Google Trends

It has long been recognised that healthcare markets display a number of significant and special characteristics that differentiate them from a perfectly competitive market, including pervasive uncertainty, unavoidable information asymmetries and the need for principal-agent relationships (Hensher, 2017). The patient-physician relationship is a classic example of the principal-agent relationship in health economics (Shih and Tai-Seale, 2012).

The insight that health information is a valuable commodity to patients dates back to Arrow's work (Arrow, 1963, Schmid, 2015). Arrow's ground-breaking paper on *Uncertainty and Welfare Economics of Medical Care* explored and described the concept of product uncertainty and consumer information in the 'medical-care market' (Arrow, 1963). The seminal paper notably outlined the concept of asymmetry of information by introducing the following concepts:

> *'Because medical knowledge is so complicated, the information possessed by the physician as to the consequences and possibilities of treatment is necessarily very much greater than that of the patient, or at least so it is believed by both parties. Further, both parties are aware of this informational inequality, and their relation is coloured by this knowledge.'*

In turn, the information asymmetry between patients and physicians sometimes raises concerns that a physician may exert a strong influence over the patient's demand for medical care and may provide services that offer more financial benefits to the physician than clinical benefits to the patient (Shih and Tai-Seale, 2012). This theory, known as supplier-induced demand, is well recognised by economists and policy-makers (Shigeoka and Fushimi, 2014, Johnson and

Rehavi, 2016, Cromwell and Mitchell, 1986, Labelle et al., 1994).

Fast-forward from Arrow's 1963 seminal paper to the 2000s: the information age (Shapiro and Varian, 2013), the emergence of the 'economics of information' (Stiglitz, 2000), and the proliferation of analyses of Google trends including for bariatric surgery (Linkov et al., 2014). In the information age, patients may be more empowered in their negotiated relationship with healthcare providers, and information asymmetries may occur that place patients in a superior information position to professionals (Shih and Tai-Seale, 2012, Schmid, 2015). Recent evidence has also suggested that patients' requirements for information consistently outstrip the expectations of clinicians (Owen-Smith et al., 2010). In turn, the increasing availability of interactive information that is accessible to healthcare consumers, most notably through the Internet and related technologies such as digital television and web television, coincides with the desire of most healthcare consumers to assume more responsibility for their health (Flaherty et al., 2015). However, other evidence suggests that information has a negative effect on health care utilisation, contradicting previous findings (Schmid, 2015).

7.1.4 Supplier-induced demand *versus* demand-induced supply: are bariatric surgery patients empowered in the information age?

In the information age, information asymmetries for bariatric surgery may emerge on the producer (physician) *or* consumer (patient) side. Under supplier-induced demand, a physician takes an action to shift the patient's demand curve in the direction of the physician's own interests. Physicians can effect such a shift, because they have more information regarding the patient's condition and treatment options than the patient (Culyer, 2014).

In contrast, under demand-induced supply the unprecedented amount of information made available through, for example, the media and Internet may reduce the information gap between physicians and more information-savvy patients (Shih and Tai-Seale, 2012). Such easy access to medical information could allow some patients to know more than their physicians on particular issues in which they have a personal interest, or to have confidence (founded or otherwise) in their own choices about these issues. This emerging phenomenon of demand-induced supply may arise due to patient empowerment through the availability of medical information through online sources and social networks. Thus patients (instead of physicians) shift the demand curve out due to a change in their knowledge or taste (Shih and Tai-Seale, 2012) (Figure 1). Additionally, this outward shift of the demand curve causes a movement up the supply curve by physicians, even though the move may be inconsistent with the physician's professional judgement (Figure 1). Quantitatively, demand-induced supply is the additional amount of healthcare services provided by the physicians at the request of patients (which could include bariatric surgery patients seeking bariatric surgery as a treatment option for obesity informed by their preoperative information gathering) that would not have otherwise been offered (Shih and Tai-Seale, 2012). The impact of the patient's request for services could coalesce with the physician's response to financial incentives (McGuire, 2000, Shih and Tai-Seale, 2012).

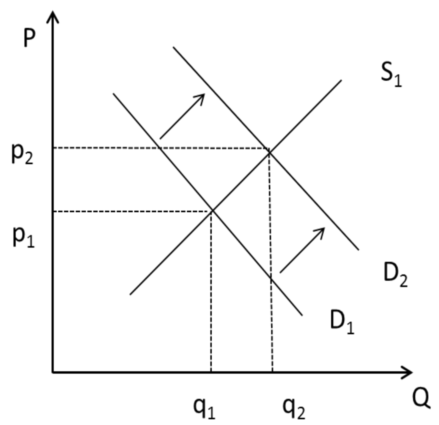
The consequent 'empowerment' of the healthcare consumer (including the bariatric surgery consumer) in healthcare decision-making is now fundamental to the patient-physician relationship, and the 'patient-healthcare organisation' relationship (Graffigna et al., 2014). Several patient-centred models have subsequently emerged to drive efficiencies in the resource-constrained healthcare environments. These models include the exchange of information between healthcare professionals and patient through consumer informatics, shared decision making, patient-centredness and patient health engagement models (Graffigna et al., 2014). It has also been suggested that patients should be given a *meaningful* seat at the table of health economic model conceptualisation and development (e.g. cost-effectiveness and cost-utility modelling) through a qualitative approach to elicit health economic impacts of an intervention that would typically be excluded or not provided with sufficient priority in reporting to the healthcare decision maker (Campbell JA, 2018)

Nevertheless, emerging trends in behavioural economics have suggested that the traditional neo-classical model is deficient in understanding over-eating and obesity (Ruhm, 2012, Cawley and Ruhm, 2011). Behavioural economics debunks the neo-classical tenet of the 'rational consumer' and instead provides practical insights into the provision of information in health policy settings under the tenet of 'bounded rationality (Matjasko et al., 2016).

7.1.5 Qualitative research methods: are bariatric surgery patients information-savvy?

The main objective of our study was to employ qualitative research methods to investigate the concept of information asymmetry for bariatric surgery patients in the information age. We aimed to achieve our objective by frequent comparison of emergent thematic categories with the pre-existing economic theories of information asymmetry, the principal-agent relationship and demand-induced supply. Through our qualitative analysis we sought to identify important information 'drivers', sources and types (including the quality and consistency of information), and the divergence of what information is 'important' to bariatric surgery patients in the pre- and postoperative periods.

Figure I In the information age bariatric surgery patients shift the demand curve from D_1 to D_2 and are at the equilibrium point p_2 and q_2 when they seek bariatric surgery from their physician. This outward shift of the demand curve causes a movement up the supply curve by physicians.



7.2 Materials and Methods

7.2.1 Quality reporting

The development of a formalised qualitative research methods checklist for focus groups and in-depth interviews (the Consolidated Criteria for Reporting Qualitative Research (COREQ) checklist) acknowledged that qualitative research explores complex phenomena encountered by clinicians, healthcare providers, policy-makers and consumers in healthcare (Tong et al., 2007). The preparation of our study's report was guided by the individual items of the COREQ checklist (Tong et al., 2007)).

7.2.2 Recruitment, study design and focus group structure

This qualitative study was conducted in Tasmania, an island state of Australia, which has a population of approximately 500,000 people with approximately 35,000 adults classified as Class 2 obesity (body mass index (BMI) $\geq$ 35 kg/m^2) (ABS, 2012). The recruitment methodology, study design and procedures for the focus groups are comprehensively outlined in previous published work (Sharman et al., 2016b, Sharman et al., 2016a, Campbell JA, 2018). In summary, ten focus groups (n=49) were conducted in the north and south of the state of Tasmania and there was a purposeful sampling of males and females, private versus public surgery, and people who were waitlisted for their surgery in the public healthcare system. Each focus group was no longer than 1.5 hours in duration, all were audio-recorded, transcribed verbatim and names were de-identified.

7.2.3 Economic data collection

The pre-existing theory of information asymmetry, the principal-agent relationship and demand-induced supply in the information age supported the initial development of health economics questions and prompts. A focus group discussion schedule was developed in liaison with the broader research team and revised during the focus group program (three month timeframe). The questions and prompts contained in the discussion schedule guided the semi-structured focus group discussions to elicit the health economics data for thematic analysis.

7.2.4 Qualitative research methods employed for data analysis

Thematic analysis underpinned by grounded theory (Strauss and Corbin, 1990, Strauss and Corbin, 1998, Liamputtong and Ezzy, 2005, Ezzy, 2013) informed the development of this study's sub and central themes through the process of open, axial and selective coding of the focus group transcripts (Campbell JA, 2018). This thematic analysis was descriptive and interpretive and facilitated by use of software (QSRInternational, 2010). Table 1 provides an outline of the process of coding in thematic analysis (Campbell JA, 2018, Ezzy, 2013).

We mixed inductive and deductive qualitative research methods. By adopting inductive and deductive theory building themes do not emerge from the data uninfluenced by the pre-existing theory (in this study asymmetry of information, the principal-agent relationship, and the subsequent concepts of supplier-induced demand and demand-induced supply). Additionally, the process of theory building involves an ongoing dialogue between data and theory in which emerging theories are repeatedly tested against the data (Figure 1, (Ezzy, 2013) (Campbell JA, 2018).

During the coding development for this study, the first author discussed the emergent sub- and central themes with the other qualitative and health economics investigators. An audit trail was kept for the project that comprised of a journal of question development, focus group sessions and refinement of questions, all coding sessions, memos, reflective notes, emails, group meetings, and individual meetings with the first author. Focus group participants' experiences are highlighted with quotations and longer verbatim quotes are italicised and indented.

Table 1: Coding in grounded theory and thematic analysis*

Open coding: • Explore the data. • Identify the units of analysis. • Code for meanings, feelings, actions. • Make metaphors for data. • Experiment with codes. • Compare and contrast events, actions and feelings. • Break codes into subcategories. • Integrate codes into more inclusive codes. • Identify the properties of codes. Axial coding: • Explore the codes. • Examine the relationships between codes. • Specify the conditions associated with a code. • Review data to confirm associations and new codes. • Compare codes with pre-existing theory. Selective coding: • Identify the core code or central story in the analysis. • Examine the relationship between the core code and other codes. • Compare coding scheme with pre-existing theory.

Source: *Adopted from Qualitative Analysis: Practice and Innovation (Douglas Ezzy 2013)*.

7.2.5 Participant characteristics

Baseline socio-demographic and clinical data are presented descriptively as mean (standard deviation (SD)) for continuous variables and frequency (%) for categorical variables. Participants' height and (current) weight data were measured and recorded before the focus group sessions. Body mass index (BMI) was calculated as weight (kg)/[height (m)]^2. Percentage total weight lost (%TWL) was calculated as (lost weight / initial weight) *100 and percentage excess weight lost (%EWL) was calculated as (lost weight) / (initial weight – [25 * height (m)^2]) *100.

7.3 Results

7.3.1 Participant characteristics

Table 2 provides participants' sociodemographic characteristics. Participants were middle-aged, predominantly female and their education levels were evenly dispersed. Clinically, for participants who underwent bariatric surgery (n=41), Mean (SD) % total weight lost (TWL) and % excess weight lost (EWL) was 25.7% (12.5) and 60.6% (28.8) respectively. Ninety-eight percent of participants were severely obese before surgery (BMI ≥35 kg/m^2) and this was reduced to 26% of participants after surgery. All participants who were waitlisted for bariatric surgery were severely obese.

Table 2: Participants' socio-demographic characteristics

Characteristics (n=49)	Participants who had undergone bariatric surgery (n=41)	Participants waitlisted for bariatric surgery (n=8)
Age years		
Mean (SD)	55 (11)	54 (8)
Sex		
(Female, n=x, %)	(n=26, %)	(n=6, 75%)
*Highest level of education**		
Category 1	(11, 27%)	(2, 25%)
Category 2	(6, 15%)	0
Category 3	(13, 32%)	(6, 75%)
Category 4	(11, 27%) *	0
LAGB (n=x, %)	(n=40, 98%)	NA
Secondary Procedure (n=x, %)	(n=6, 15%)	NA

Notes:
SD = standard deviation; LAGB = Laparoscopic adjustable gastric band.
*Highest level of education: category 1 = year 10 or less; category 2 = year 11 and/or 12; category 3 = certificate, diploma or trade; category 4 = university.

7.3.2 Thematic analysis

The core finding that emerged from our interpretive analysis was that irrespective of the sources and types of information that the participants used to inform their decision to undergo bariatric surgery, most participants' decision to undergo surgery would be unlikely to change.

We found that both publicly and privately treated participants identified similar information types and sources before and after surgery. We also found that psychosocial 'drivers' for information gathering and interpretation were fundamentally important *before* surgery and that the quality and consistency of validated, objective healthcare information became more important to participants *after* their bariatric surgery.

Key themes that emerged from our thematic analysis are outlined below.

(i) Divergence of information sources before and after bariatric surgery

In the information age, bariatric surgery patients access and interpret a wide-range of information sources before and after their bariatric surgery. Importantly, our study found that the drivers to seeking out particular information sources about bariatric surgery pre- and postoperatively were substantially different. Our study also found that information sources diverged pre- and postoperatively.

Before surgery, many participants discussed accessing information more informally through social networks such as family and friends, the Internet or medical television programs. For example, participants stated 'I had looked up the Internet', 'I did a bit of research on the Internet', 'the girlfriend had it done' and 'any medical show on TV I watch'. For example, one participant suggested that these more informal information sources were important in their decision-making to undergo bariatric surgery:

> *I know a couple of my friends – well my wife's friends had, had it and it worked for them. Um I didn't know much about it. I did a bit of research on the internet um thought, "Yeah it's a good idea* (male, public system)

Some participants described the importance of social networks for gathering their information about bariatric surgery before they decided to have bariatric surgery. These included participants' partners, close family and friends, or speaking to acquaintances who had undergone bariatric surgery. For example, one participant outlined the benefit of speaking to 'lots of people' to gain information about their personal experiences before making the decision have bariatric surgery:

> *I've just spoken to – I've just spoken to lots of people that have had the lap-band surgery you know what their experiences of it were. Some people have said it's the best thing they've ever done. There's been other people that said it's not the answer to everything, it's not been easy at all (*female, public system)

Nevertheless, some participants described situations where the physician (including at public information sessions) explained the lap-band procedure and expectations regarding dietary and lifestyle changes, coupled with the provision of a 'lap-band' information booklet. Some people described using an 'information booklet' or flyer with accompanying Internet searching for information. To illustrate, one participant said:

> *Well when I first made the initial appointment to see the specialist, I was given a booklet…had to take that home and read it. So basically a lot of the information came from there, also doing internet research. Mainly a lot studies I sort of looked at came from America, where it had been done – trialled over there quite a bit; not here in Australia. Yeah so that was the main areas where I got mine* (male, public system)

After surgery, many participants acknowledged that the information sources they accessed before surgery were insufficient to appropriately inform them about their postoperative experiences and complex physical and psychological HRQoL needs. These participants suggested that more targeted, high-quality healthcare information and support (particularly psychological) should be an important consideration before surgery. To illustrate, Table 3 provides verbatim quotes that highlight participants' acknowledgement of key information gaps regarding their psychosocial HRQoL impacts or needs after their bariatric surgery.

(ii) Weight status is only one factor influencing HRQoL: psychosocial HRQoL as a key 'driver' for gathering information

In the information age, high-quality, validated, consistent and targeted information about bariatric surgery is important to bariatric surgery patients. Our study found that the complexities of many focus group participants' psychosocial HRQoL before bariatric surgery and their subsequent shift in perceptions about relevant psychological information needs after undergoing bariatric surgery informed many participants' understanding about their preoperative healthcare.

Before surgery, we found that focus group participants discussed a tremendously complex interweaving of psychosocial drivers for seeking information about bariatric surgery and their perceived healthcare literacy and empowerment before they underwent bariatric surgery. Many participants discussed these psychosocial or emotional drivers for seeking surgery that included the way they felt about themselves and their emotions. These complex socio-emotional drivers were linked to discussions about 'seesawing weight'. One participant discussed the 'seesawing weight' as an illness:

> *It became an illness – or it did become an illness for me trying to go up and down. I did go down very quickly but I'd go up twice as much, and twice as fast. And that seesawing for me was a mental illness. It was not a nice place to be, and I'm never going back there, ever in my life. That's why I say I came to a place of acceptance* (female, private).

Importantly, our study found that it was only after bariatric surgery that many participants fully acknowledged the complexity of their psychosocial HRQoL. Many participants discussed the psychosocial and socio-emotional drivers that motivated them to undergo bariatric surgery. For example, a couple of participants used language like 'magic-bullet effect' and 'mindset', others talked about their 'comfort eating', nevertheless these participants appeared to have only acknowledged these psychosocial drivers after they had their surgery. Most of these participants also discussed the need for high-quality and validated healthcare psychological information and support before their surgery to address their mindset.

For example, one participant suggested that despite gathering information about lifestyle and eating practices, psychological information was important after surgery:

> *We've done some research, we know what it's about, we know what happens, we know that it's going to really severely affect the way that you eat, and all that kind of thing. But I*

guess no one really prepares you for the psychological stuff. The, "Yes, you might not be hungry anymore but the habits are still there." (female, private system).

(iii) Information regarding the management of physical health impacts after bariatric surgery

Physical health impacts that are not directly associated with weight loss (for example, improved HbA1c as an indicator of diabetes status, blood pressure as an indicator of cardio-vascular health or joint pain) are important postoperative considerations for people who undergo bariatric surgery. Nevertheless, many participants did not particularly seek information regarding these types of physical health impacts, nor did they know about or understand ways to manage other potentially debilitating physical impacts that would enable a smoother transition after their bariatric surgery. To illustrate, many participants discussed physical health concerns such as 'dehydration', 'not being able to get enough fluids', 'anaemia', 'vomiting', and regurgitation of food. Some participants described unexpected emergency department visits or hospital admissions due to fluid and electrolyte deficiency (e.g iron deficiency and dehydration) or food bolus obstruction. In regard to dehydration and food intake one participant said:

> *I can't seem to find the right balance. I'm either like you [another focus group participant] for days on end and end up in the LGH [Launceston General Hospital] hooked up to a drip because I'm so dehydrated, or I'm able to eat more than what I should.* (female, private system).

In regard to maintaining a clinically acceptable fluid balance another participant said:

> *Liquids were one of the hardest things for me; still are. That's why everywhere I go, I take my drink bottle with me, because that's how I drink my liquids. I have to keep slowly [drinking] all day, and I'm sure others are the same, otherwise I can't – don't get enough*

fluids. And it's just something you learn to do; something – you learn to manage it. (female, private system).

Some participants described unexpected physical symptoms that occurred in the first few days (and meals) after their gastric band adjustment that were both physically and psychologically distressing. For example, one participant described a food blockage situation when she was out at a restaurant the evening of the band adjustment and she said:

> *Yeah, that's what it feels like. You're just so shocked [Previous speaker: Oh it is. It's like this pain in your chest; you can't breathe], and I think I almost lost it the first time that happened, I remember turning gray and thinking, "How – what on earth's going on?" I mean, now I know how to cope with that." But at the time there's no feedback on what to do when that happens.* (female private system).

(iv) Divergence of information types and sources: would patients still undergo bariatric surgery?

The bariatric surgery patient's decision to undergo bariatric surgery is generally preceded by sustained periods of psychosocial experiences related to 'years of dieting', 'seesawing weight', 'ballooning' weight, 'hitting three digits' (in kilograms) on the scales, and stigmatisation and discrimination. Despite most participants' transitional period after surgery that was marked by health illiteracy about some of the postoperative psychosocial considerations and physical health impacts (as outlined in the key themes above), most participants said that they would still undergo the surgical procedure: 'I'm pleased I've had it done; I just wish there was more education, more help to get me through to being okay'. One participant articulated that:

> *I'm not sorry I had it done, because at the time I was ballooning and it stopped that and I lost 30 kilos – which I still have masses to lose – but it stopped that progression of going towards death at a rate of knots, I suppose. So I'm not sorry I had it done.* (female, private

system).

Another participant said that:

> *I am really happy that I've had it done. And I would never want it to come out either. Because I don't think I trust myself. Because of that mental thing that's never been addressed or whatever, if I had it out I reckon I'd just put all the weight back on again. That's what scares me. So, I wouldn't – even – and this is what I've been this way now.* (female, private system).

Table 3: Examples of verbatim quotes that highlight the acknowledgement of psychosocial support needs after bariatric surgery that were not identified before bariatric surgery.

Full quotation
How psychologically it works. And how much of a trauma it is that you've actually got to really retrain yourself in thinking, "I'm not hungry," because most of us have been binge eaters, and comfort eaters, and whatever. (female, private system)
Yeah that's what I found too. In the first 12 months the psychology of the whole things is the biggest battle [New speaker: Good point]. It's ah let's – you know the truth's the truth, let's face it – every big person ah loves food, eats fast, and eats plenty of it you know. You know so we've had lap-band surgery and ah we've adjusted it up so now the ah psychology of it where we can't eat fast, we can't eat a lot of it and ah – yeah that's probably the most difficult part over the 12 months…And it does probably take 12 months wouldn't you say, to get that psychology right? Where that's – forget about somebody eating a big baked meal over there, might smell nice, but you know darn well that you can't eat and ah [New speaker: That's right]. (male, public and private system)
Yeah it stopped you eating too much, and that's what I'm now right into working – I'm still battling – my mindset never went away with the operation [New speaker: No, no], and that's what I'm returning to. It's still there – that's what I found – the same psychology's still in my head. I don't have that thing that makes me – I can't be feeling ill because I literally – it doesn't do anything for me anymore. I've still got a little bit of obviously tightness there, and I can't go crazy. But I can still – it's not working for me, and I'm thinking, "Geez, that whole mindset is still there and it never went away. (female, private system)
My family told me that I should go and get my head sorted. So I've just been doing it. (female, private system)
So it isn't a curable. You've got to do head work for it to be successful as well. (female, private system)
It really is a psychological issue and there is really no help for that basically. Nobody tells you or it's really hard to get knowledge, that's what I found. (male, public and private system)
You know, you've still got – even though you've had surgery and you've lost weight, there is so much more mind stuff, which in my experience, isn't really addressed. You know your body's changed, you're a different shape, you're a different person – I certainly feel like I'm a different person than I was then – but there's still a lot of mind stuff happening in there. There really – unless you want to go and get it privately addressed – isn't addressed it just goes, "Okay, you know I'm smaller now, I can – you know I can walk better, I can do this" – but there's still all that stuff going in your head (female, private system)
It's also the psychology of your eating patterns before your lap-band. If you're a comfort eater – or you know, I eat when I'm happier, I eat when I'm sad, I eat when I'm disappointed. I eat when it's Monday, I eat when it's Tuesday. So if the – if your eating patterns and your psychology are like that, as the other lady alluded to, nothing is done to address those issues. (female, private system)

7.4 Discussion

Our study is the first health economics study to use qualitative research methods to investigate bariatric patient's lived experiences with the pre-existing theory of information asymmetry in the marketplace for bariatric surgery. Importantly, through sophisticated grounded theory we adopted the process of frequent comparison of emergent thematic categories from our qualitative data with the pre-existing economic theories of asymmetry of information and the principal-agent relationship (particularly demand-induced supply) for bariatric surgery patients in the information age. By exploring bariatric surgery patients' experiences we found that there were substantial inconsistencies in preoperative and postoperative information drivers, sources and types for the study population. Importantly, we found that consumers of bariatric surgery *perceived* that they were informed by the information sources they accessed and used in their decision-making to seek or undergo bariatric surgery. We also found that psychosocial 'drivers' for information gathering and interpretation were fundamentally important *before* surgery and that the quality and consistency of validated, objective healthcare information became more important to participants *after* their bariatric surgery.

7.4.1 Bariatric surgery in the information age: demand-induced supply and postoperative transition

Our study endeavoured to understand the potential consequences of the emerging concept of demand-induced supply in the information age (in contrast to supplier-induced demand) in today's marketplace for bariatric surgery where demand-induced supply has been defined as the phenomenon that patients move the demand curve out due to a change in their knowledge or taste. Importantly, our study's findings revealed that most focus group participants' decision to undergo bariatric surgery would not change regardless of their postoperative health literacy.

We suggest that preoperative information gathering by the population of bariatric surgery patients is likely to have resulted in the outward shift of the demand curve as illustrated in Figure 1 preoperatively, and that despite the identification of inadequate health literacy postoperatively, most bariatric patients would still undergo their surgery. The important point here is that in the information age bariatric surgery patients perceive that they are empowered by information and perhaps seek surgery that they may not have otherwise sought.

One of few studies (and the first study) to investigate the concept of demand-induced supply (described as physician-enabled demand) found the variable with the strongest impact on physician-enabled demand was a variable that measured the proportion of patients who provided medical information at the physician's practice (Fang and Rizzo, 2009). This study also concluded that the recent movement towards consumerism in healthcare will arm the consumer with more information and should be the subject of future research directions.

Our qualitative health economics study found that in the information age, most focus group participants would still undergo their bariatric surgery notwithstanding unexpected postoperative physical and psychological health impacts. Despite the forces of demand-induced supply that could have caused the outward shift of the demand curve, the key point is that high-quality, targeted and endorsed healthcare information preoperatively may adjust *individual* choices regarding bariatric surgery, and there could be a smoother postoperative transition after surgery. More specifically, our results suggest that appropriate pre-and postoperative information sources and types would enable these patients to better manage their psychosocial and physical health related quality of life transition after surgery. Additionally, there was a substantial divergence between information sources, types and drivers before and after bariatric surgery. We found that many participants accessed preoperative information through online sources or their family and friends (i.e. social networks). We also found that psychosocial drivers were fundamentally important before surgery and that the quality of healthcare information became more important to bariatric surgery patients after their surgery.

Recent evidence has found that the Internet is an important source of information for morbidly obese patients who are potential candidates for bariatric procedures (Corcelles et al., 2014). Their study found that bariatric surgery candidates viewed poor quality and content of information on the Internet. They concluded that while the Internet is a vast resource, to realise its full potential it is necessary to direct consumers to high quality information and to teach them how to assess the quality of information (Corcelles et al., 2014).

We found that participants recognised the value of targeted, high-quality and consistent information from healthcare professionals after they had their bariatric surgery. Nevertheless, the challenge is to motivate bariatric surgery patients to access and understand the intrinsic value of high-quality, validated, relevant information preoperatively. We suggest that poor health literacy for bariatric surgery patients preoperatively will translate to poorer HRQoL and health economics outcomes. For example, unexpected emergency department presentations and hospitalisations due to poor management of fluid and electrolyte imbalance that could be avoided with improved knowledge from the outset of surgery. In turn, we suggest that a smoother postoperative transition would also translate to decreased burden on healthcare resources.

Our broader qualitative program of work also identified that providers of bariatric surgery should discuss support needs and accessibility regularly with patients especially in the first year postoperatively and following significant change in a patient’s life (Sharman et al., 2016a).

7.4.2 The economics of risky behaviour: bounded rationality

Emerging literature in behavioural economics postulates that mainstream neoclassical theory is deficient in describing the complex nature of the economics of the obesity epidemic. A recent study regarding the application of behavioural economics to public health policy suggests that under the behavioural economic theory of 'bounded rationality', rationality in decision making is curtailed by a lack of information, cognitive limitations, and a finite amount of time to make a decision (Matjasko et al., 2016). The study also found that people may also have finite amounts of willpower and experience decision fatigue, and that all public health policy makers and providers should simplify how information is presented in order to make it easy for people to use (Matjasko et al., 2016).

Our study has identified that validated and targeted preoperative information is essential to rational in decision-making of bariatric surgery patients. High-quality, consistent and accessible information should be provided to enable a smoother postoperative transition for bariatric surgery participants. Our study also suggests that the challenge could be in motivating these patients to access and understand the value of this validated information.

7.4.3 The economics of emotional capital

Our broader program of qualitative work regarding people who have been waiting for or undergone bariatric surgery has also taken the concept of psychosocial health-related quality of life a step further and identified 'emotional capital' as a fundamental driver for participants seeking bariatric surgery and for the short- and long-term success of their bariatric surgery (Campbell JA, 2018).

In regard to information sources and needs, coupled with rational (or bounded rationality) decision making within the constraints of recently identified emotional capital drivers, we also suggest that it is important to recognise that emotional capital drivers may dominate negatively preoperatively (when people don't want to leave their own homes before they have their surgery because of their obesity), and perhaps positively after surgery (where clinical and physical concerns that should be addressed may in fact be overridden by emotional capital factors of feeling ‘respected’ and ‘good’ because of their weight loss) (Campbell JA, 2018).

7.4.4 Qualitative research in health economics

It has been argued that health policy development, research, and management could benefit from more in-depth, textured descriptions of what actually happens in practice settings, healthcare markets, and patients’ lives (Weiner et al., 2011, Greenhalgh et al., 2016, Campbell JA, 2018). In regard to the market for bariatric surgery, our qualitative study has particularly identified the psychological drivers that influenced the participants’ preoperative information gathering. It has also identified the acknowledgement of pre- and postoperative health illiteracy postoperatively.

This qualitative study has highlighted the strengths that qualitative research methods can bring to health economics study design. By listening to the ‘other’; by listening to our participants’ stories and then considering and analysing the spoken word through verbatim transcripts, we have provided health economic and policy decision-makers with a deeper contextual understanding about information in the bariatric surgery marketplace. From a research translation perspective, this means that we have identified important health economics findings that can be provided to decision-makers not be identifiable through traditional quantitative approaches.

7.4.5 Limitations

The key limitation to our study was that the study was based on people who had been exposed to information regarding bariatric surgery who had subsequently decided to opt for the surgery including those people on the waitlist who have had their bariatric surgery. It is suggested that a sample of partcipants that was exposed to information regarding bariatric surgery and then decided not to have the bariatric surgery should be the subject of future research. Another key limitation to our study was that the scope of our investigation was restricted to focus group data. Another limitation was that we did not include a qualitative investigation of physician behaviour.

The strengths of our study included the use of qualitative research methods to identify key knowledge gaps in regard to the information asymmetries for bariatric surgery patients where the economic component of the focus group discussions were embedded and thus identified during discussions of the broader 'lived' experiences of participants. Our study was informed by a relatively large sample size for qualitative research (n=49), with diversity of participants' treatment modality (i.e. public/private/waitlisted), and socio-demographic characteristics. Finally, our research team embodied a combination of knowledge and skills of experienced qualitative researchers and health economists from research and policy-making backgrounds to enable a multi-disciplinary investigation of the predominantly quantitative health economics research of bariatric surgery.

7.5 Conclusions

This study found that in the information age, there was a divergence of information sources and needs pre- and postoperatively for bariatric surgery patients. We recommend that high-quality and consistent information sources be targeted towards the psychosocial domains and even the emotional capital of pre- and postoperative health. We also recommend that appropriate healthcare information be provided to enable a smoother transition for the management of physical health impacts such as postoperative dehydration and electrolyte imbalance which can result in unexpected hospitalisation. A smoother postoperative transition would likely translate to less burden on the healthcare doll

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Chapter 8: A cost-outcome study: A real-world investigation of long-term inpatient hospital utilisation and costs for a retrospective cohort of bariatric surgery patients in an Australian public hospital system based on Australia's Activity Based Funding model.

Preface

Chapter 8 presents the final study of this mixed-methods PhD research regarding the health economics of obesity and bariatric surgery. Chapter 8's applied quantitative costing study is the first study within the Australian public hospital setting to report on individual episodes-of-care and costed patient-level pathways for primary, and secondary/tertiary bariatric surgery informed by Australia's Independent Hospital Pricing Authority's Activity Based Funding model.

The NHMRC partnership project between the Tasmanian State Government and the University of Tasmania was, in part, developed to investigate and identify direct medical costs for a retrospective cohort of bariatric surgery patients in Tasmania, based on the Activity Based Funding model. Prior to this study, accurate individual patient-level resource use and costs of bariatric surgery for people with severe obesity waitlisted for, and who then undergo bariatric surgery in the Tasmanian public hospital system were not known. The findings of the systematic review in Chapter 2 particularly guided the study's investigation of the patient-level unit costs, the costs of waiting for bariatric surgery, subgroup analyses, and the accurate cost of complications and reoperations over a long time horizon. The study's strategic research alliance exploited the economic concepts of heterogeneity of human capital, division of labour and comparative advantage to drive a clinical costing team for bariatric surgery in the Tasmanian public hospital system. Data were extracted on an individual patient basis to track the primary Activity Based Funding episodes-of-care and associated length-of-stay and costs attributed to each patient pathway before and after primary bariatric surgery. The study found that the cost of providing the primary laparoscopic adjustable gastric band (LAGB) bariatric procedure compared with the sleeve gastrectomy procedure is similar. The study also suggested that prevalent LAGB device-related costs could be mitigated with alternative surgical methods such as sleeve gastrectomy (rather than the prevalent LAGB) within the Tasmanian public hospital system. Another interesting finding from subgroup analysis was that the average cost for an episode-of-care reduced from the first year after surgery for people with diabetes.

Overall this study's findings suggest that bariatric surgery in the Tasmanian public hospital system may be an attractive value-based option in the longer term: bariatric surgery realised health benefits (reduced inpatient episodes-of-care) and reduced costs at year 3 postoperatively. Costs could be mitigated by substituting LABG with SG when clinically appropriate, taking into account our small SG sample size. Three years postoperatively, episodes-of-care and costs reduced substantially versus preoperatively, particularly for people with diabetes/cardiovascular disease. One year preoperatively, the study population recorded the highest number of inpatient episodes-of-care and costs. We also found that the cost of secondary and tertiary surgery maximised at year 2.

This study was presented at the Australian Health Economics Society Doctoral Workshop on 20 September 2017. The workshop Discussant and participants provided valuable and positive feedback that has been incorporated into the draft. The positive observations included comments regarding the applied nature of the project and the identification of each patient pathway, resource use and cost from the primary surgical procedure through to the secondary and tertiary procedures.

Our project partner has stated that the findings from this study are of policy-changing interest, particularly when the findings of this study are pooled with the findings and recommendations of my PhD research's investigation regarding the health economic evaluation of bariatric surgery (Chapter 2), the assessment of health-related quality of life for people waiting for or who had received bariatric surgery in the public and private healthcare systems (Chapters 3, 4 and 5) and the qualitative research regarding bariatric surgery patients' lived experiences (Chapters 6 and 7).

The holistic summary of this PhD's body of work on the health economics of obesity and bariatric surgery internationally, nationally and locally within Tasmania is provided in Chapter 9 of this thesis.

Please note that the Reference and Abstract style of this paper reflects the submitted journal's style. This chapter is under review at PharmacoEconomics Open.

Impact factor: New journal.

Campbell JA, Hensher M, Davies D, Green M, Hagan B, Jordan I, Venn A, Kuzminov A, Neil A, Palmer AJ. A cost-outcome study: A real-world investigation of long-term inpatient hospital utilisation and costs for a retrospective cohort of bariatric surgery patients in an Australian public hospital system based on Australia's Activity Based Funding model.

Abstract

Background: Within the Australian public hospital setting, no studies have previously reported total hospital utilisation and costs (pre/postoperatively), and costed patient-level pathways for primary bariatric surgery and surgical sequelae (including secondary surgery) informed by Australia's Independent Hospital Pricing Authority's Activity Based Funding (ABF) model. We aimed to provide our Tasmanian State Government partner with information regarding key evidence gaps about the total costs of bariatric surgery (including before and after surgery, types of surgery, and comorbidities) and the costs of surgical sequelae. We also aimed to provide some direction regarding the types of bariatric surgery offered within the Tasmanian public hospital system.

Methods: Data were extracted from administrative sources routinely collected, clinically-coded/costed according to ABF. Aggregated ABF (2015 Australian dollars) inpatient episodes-of-care for the surgical procedure and before and after surgery associated length-of-stay and costs (including micro-unit costs of operating theatre, pharmacy, ward and salary costs) were investigated for the fiscal-years 2007/08 to 2015/16. Sensitivity (cost outliers) and subgroup analyses (people with diabetes, cardiovascular disease and BMI cut-points) were also conducted.

Results: N=105 publicly-waitlisted severely-obese patients with multi-morbidity underwent primary bariatric surgery (laparoscopic adjustable gastric band (LAGB) n=89; sleeve gastrectomy (SG) n=16) in Tasmanian public hospitals. Annual total costs (TC) 1 year preoperatively were $434,710 and 3 years postoperatively were $122,820. TC and episodes-of-care decreased at 3 years postoperatively for the entire cohort. The average cost/episode-of-care decreased in the first year postoperatively for people with diabetes, from $6,984 to $5,610/episode-of-care. TC (pre/postoperative over 8 years) for *all* inpatient episodes-of-care (n=779 episodes-of-care) were $5,791,530. When the ten identified cost outliers were omitted from the total cost, this cost reduced to $4,570,275. Mean costs for primary LAGB and SG bariatric surgery were $14,071 and $14,448, respectively. Twenty-seven LAGB patients (30%) required surgery due to surgical sequelae (including revisional/secondary surgery) (n=58 episodes-of-care), and 56% of these episodes-of-care were secondary LAGB device-related (mostly port/reservoir-related) with mean costs of $6,031.

Conclusions: Our patient-level analyses provided much needed information regarding the costs of bariatric surgery to the Tasmanian public hospital system. Three years postoperatively, episodes-of-care and costs reduced substantially versus preoperatively, particularly for people with diabetes/cardiovascular disease. Costs could be mitigated by substituting LABG with SG when clinically appropriate, taking into account our small SG sample size. We recommend that a larger confirmatory study regarding SG versus LAGB be undertaken at a more granular level of ABF costing.

8.1 Introduction

8.1.1 Obesity and bariatric surgery: the Australian context

The obesity epidemic is a complex public health, economic and strategic policy problem [1-4]. In Australia, over 60% of adults are overweight or obese, and in line with global trends, the rate of severe obesity (body mass index (BMI) ≥35 kg/m²) is increasing more rapidly than overweight and obesity (overweight BMI 25–29.9 kg/m²; obesity BMI 30–34.9 kg/m²) [5-7]. Given this increasing trend of severe obesity, recent clinical literature also describes a fourth class of obesity known as 'super-obesity' defined as a BMI of ≥50 kg/m² [8].

The most recent estimate contained in the published literature of the total annual direct cost of overweight and obesity in Australia in 2005 was 21 billion Australian dollars: this estimate was substantially higher than previous estimates [9]. An international study has established that costs rise rapidly in the range of severe obesity [10].

The Australian National Health and Medical Research Council's clinical guidelines recommend bariatric (obesity, weight-loss, metabolic [11]) surgery as a treatment option for severe and resistant obesity [12]. In 2014–15, there were more than 22,700 weight loss surgery separations in Australia, most of which involved a primary procedure (79.4%) [5]. The majority of these bariatric surgery separations (88.0%, or 20,000 separations) occurred in private hospitals [5].

A recent Australian study determined that the potential demand for publicly- and privately-funded bariatric surgery in Australia was 882,441 adults aged between 18-65 years [13]. Importantly, 45.8% of these potential bariatric surgery candidates had no private health insurance [13].

Importantly, another recent qualitative health economics study found that of the people who partially or fully self-funded their bariatric surgery experienced economic burden to do so [14]. This qualitative health economics study also found that some people were accessing their superannuation to fund their surgery because they either had no private health insurance, or they had to pay the concomitant health insurance gap [14].

The Australian healthcare system presents a complex and fragmented set of arrangements between the public (two tiers of government) and private sectors [15]. The Commonwealth government holds the major revenue raising power. The state governments operate public hospitals which account for about two-thirds of all hospitalisations and provide emergency department visits without charge. Australia's National Health Reform Agreement established the new basis for the Commonwealth's contribution to public hospital funding based on a hospital's casemix and defined as Activity Based Funding (ABF) [16, 17]. Constrained public sector budgets contribute to the incapacity of the Australian public health system to address the problems of severe obesity increasing more rapidly than obesity [1, 18]. This problem is reflected internationally [15, 19-21]

8.1.2 Real-world data to inform health economic decision making

Health decision-makers involved with coverage and payment policies are increasingly seeking information on real-world outcomes on which to base their decisions recognising the importance of evidence that goes beyond information collected in randomised control trials [22].

A recent Australian Institute of Health and Welfare (AIHW) report regarding weight loss surgery in Australia that used Medicare data to analyse the costs of bariatric surgery, suggested further research could report on 'typical patient journeys' incorporating a broad range of direct medical costs (rather than just analysing Medicare linked data). The report stated that the ability to track and analyse patient journeys from primary through to surgical sequelae (including secondary surgery) would greatly assist in understanding the broader relationships between primary surgical procedures and subsequent adjustments and revisions and their associated costs [5]. Notably this AIHW report only provides aggregate figures for the number of bariatric surgery separations for some Australian jurisdictions, including Tasmania, suggesting a key evidence gap [5].

8.1.3 Objectives of this study

Our comprehensive systematic review of the health economic evaluations of bariatric surgery found that bariatric surgery is cost-effective or potentially cost-saving for severely obese patients (body mass index (BMI) $\geq$ 35 kg/m^2) with concomitant diabetes [1]. However, the review also found that costs due to complications and reoperations of bariatric surgery were only incorporated in one-third of the included studies [1]. Additionally, when these costs were included, a *conservative estimate* of the costs of complications or re-operations, or low probabilities of these events were assumed [1]. Another recent systematic review regarding reoperations after secondary bariatric surgery found that despite being poorly reported, risks of reoperations and long-term complications and tertiary bariatric surgery are higher than usually reported risks of short-term complications [23]. The most recently published Australian cost-utility study of bariatric surgery took rates of complications and reoperations from the literature, rather than from the administrative hospital database that was used for the costs of the initial bariatric surgery therefore suggesting another conservative estimate [24]. Furthermore, the base case for the cost-utility study assumed a severely-obese female cohort of 30 years of age with no co-morbidity at the time of the operation [24].

While previous attempts have been made to quantify the costs of bariatric surgery in an Australian setting [24], they did not use the Independent Hospital Pricing Authority's ABF model. An Australian National Health and Medical Research Council partnership project between the Tasmanian State Government and the University of Tasmania was, in part, developed to investigate and identify direct medical costs for a retrospective cohort of bariatric surgery patients in Tasmania, based on the Australian Independent Hospital Pricing Authority's ABF model.

Prior to our current study regarding bariatric surgery in the Tasmanian public hospital system, accurate resource use and costs of bariatric surgery for people with severe obesity waitlisted for, and who then undergo bariatric surgery in the Tasmanian public hospital system have not been known. More specifically, our State Government project partner does not know the hospital utilisation and costs for people with severe obesity (predominantly with concomitant comorbidity) who receive bariatric surgery in the Tasmanian public hospital system, informed by the Australian Independent Hospital Pricing Authority's Activity Based Funding Model. Nor does our project partner know the relative costs of the two types of bariatric surgery offered in the Tasmanian public hospital system. Therefore, our research aimed to address a key evidence gap by providing our State Government partner's key decision-makers with hospital utilisation and cost analyses to inform policy decisions about prioritisation and access to public hospital resources for bariatric surgery in the Tasmanian public hospital system.

More specifically, we aimed to provide evidence regarding the total costs (over a long time horizon) of providing public healthcare resources to people waiting for, and who then receive, bariatric surgery in Tasmania. We also aimed to provide evidence regarding hospital utilisation and costs for LAGB and SG, both primary and surgical sequelae of bariatric surgery (including secondary and tertiary surgery) in Tasmania.

8.2 Methods

8.2.1 Study design

(i) Validated guidelines

This study has been conducted in accordance with validated guidelines including the Consolidated Health Economic Evaluation Standards (CHEERS checklist) (Appendix 1) [25], the Independent Hospital Pricing Authority Patient Costing Standards version 3.1. [17], the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement [26], and the Tasmanian Department of Health and Human Services (DHHS) Patient Level Costing Policy and Manual (October 2016) [27]. We also reported in accordance with the International Society for PharmacoEconomics Outcomes Research Real-World Data Taskforce Report [22], which states that real-world data are essential for sound coverage and reimbursement decisions: *context* matters greatly in determining the value of a particular type of intervention in any circumstance [22].

(ii) Study setting, the strategic research alliance, information sources and economic perspective

This retrospective health economics study was part of a much broader mixed-methods partnership project between the Tasmanian State Government and the University of Tasmania. The study's strategic research alliance exploited the economic concepts of heterogeneity of human capital [28], division of labour [29] and comparative advantage [30] to drive a clinical costing research team for bariatric surgery in the Tasmanian public hospital system between the university researchers and the departmental officers. The team comprised of: state government officials who were experts in the department's administrative databases, clinical coding and costing (under the auspices of the Australian Independent Hospital Pricing Authority's ABF model that informed the costs extracted for analyses), database construction and raw cost data extraction; university researchers expert in clinical research, health economics and epidemiology; and a state government official who was a health economist, policy-leader and decision-maker within the DHHS.

Patient sociodemographic, clinical, resource use and cost data were extracted from the DHHS's Patient Management System and Clinical Cost databases.

The costing was performed primarily from the Tasmanian Government's perspective and to a lesser extent the Commonwealth Government's perspective (under the National Health Reform Agreement [16]). Relevant ethics approvals were obtained from the University of Tasmania's Health and Medical Human Research Ethics Committee.

(iii) Study population

From the patients who were enrolled on the waiting list for bariatric surgery from 1 January 2008 to 31 December 2013 the study population was defined as all patients who had received primary bariatric surgery in a Tasmanian public hospital (i.e. not contracted-out into the private hospital sector for their surgery, nor treated elsewhere privately), and subsequently ABF costed for the fiscal years 2007/08 to 2015/16.

Patients who were then identified from the waiting list (1 January 2008 to 31 December 2013) as having received primary bariatric surgery in the Tasmanian public hospital system over this time horizon were then classified by surgery type: primary laparoscopic adjustable gastric band (LAGB) and primary sleeve gastrectomy (SG). Importantly, these were the only forms of bariatric surgery performed in Tasmania during this period.

(iv) Activity based funding model

A bottom-up costing methodology (in relation to the DHHS predefined ABF cost buckets) for resource use and costing was used [27]. Within the ABF model, the DHHS focused on costs at the patient level. The DHHS states that a consistent approach to identifying how individual patient costs are built-up can help organisations understand where variations arise within a patient pathway, for example, in theatres, wards or diagnostics [27]. The DHHS's development of patient-level costs builds costs from the bottom-up, identifying where possible the resources used in treating individual patients – for example, prosthetic devices (such as LAGB-appliance), the intensity of nursing resources and indirect or overhead costs such as the costs of the payroll or finance team through appropriate allocation and apportionment methods [27].

More specifically, the DHHS costing methodology [27] adheres to 6 steps for ABF patient-level costing [17]: (1) 'define the patient care to be costed' - the first step is to identify the elements of patient care that need to be costed. Figure 1 provides an outline of the DHHS process to identify the patient care to be costed; (2) 'identify the activities' - to assign costs accurately to a defined element of patient care, the activities associated with delivering that care need to be accurately identified; (3) 'identify the relevant costs' – once the element of patient care to be costed has been defined, and associated activities and resources identified, the next step is to determine the relevant costs incurred in delivering the patient care; (4) 'classify costs' – after identifying costs for an element of patient care, the next step is to analyse and classify these costs. Under ABF, the Independent Hospital Pricing Authority's costing standards classify costs based on direct and overhead costs and fixed, semi-fixed and variable costs; (5) 'assign costs' – once the resource costs and activities underpinning the element of patient care to be costed have been fully analysed and understood, the next step is to assign the resource costs to the respective elements of patient care [costs can be attributed using the following methodologies (Actual use, Weighted costs, Apportionment based on relevant statistics such as floor area)]; and (6) 'validate the outputs' – basis checks are undertaken to ensure the costing is accurate [27]. This study investigated the *aggregated* ABF costs.

An episode-of-care is defined by the Australian Independent Hospital Pricing Authority as 'A phase of treatment from admission to separation. An admission may be 'statistical' in that the patient changed from one type of admitted patient category to another (between any two of acute, rehabilitation, palliation, or non–acute) without being separated from the hospital. It follows that there must be a 'statistical separation' before every statistical admission' [17]. Our study population's primary bariatric surgery inpatient hospital admissions and all their preoperative and postoperative inpatient hospital admissions (for the pre-defined time horizon of 2007-8 to 2015-16) were extracted to generate a unique episode-of-care number that was costed according to ABF[17, 31].

Table 1 provides examples of ICD-10-CM, AR-DRG, and procedure codes of interest for the primary LAGB surgery [32, 33].

Figure 1: The Tasmanian Department of Health and Human Services patient level costing process mapping (Source: Patient Level Costing Guidance Manual October 2016).

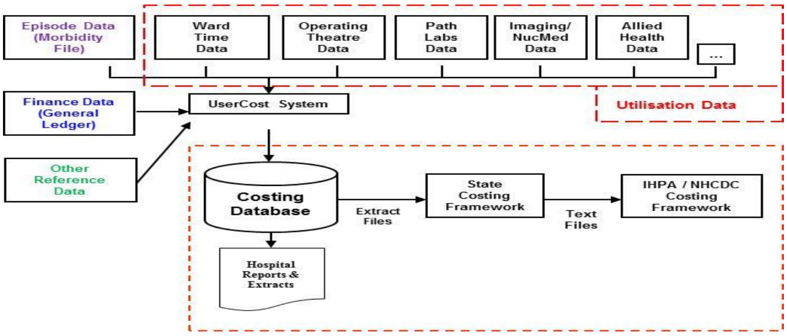


Table 1: Examples of ICD-10-CM, Australian Refined Diagnostic Related Group (AR-DRG) codes, and procedure codes of interest for primary bariatric surgery.

Principal diagnosis	Description
ICD-10-CM codes	
E65	Localised adiposity
E66.8	Other obesity
E66.9	Obesity, unspecified
E10	Type 1 diabetes mellitus
E11	Type 2 diabetes mellitus
AR-DRG codes	
G02A	Major Small and Large Bowel Procedures, Major Complexity
G02B	Major Small and Large Bowel Procedures, Intermediate Complexity
G05C	Minor Small and Large Bowel Procedures
K04A	Major procedures for obesity
K04B	Major procedures for obesity
K04Z	Major procedures for obesity
K12Z	Other Bariatric Procedures
K60	Diabetes
K60A	Diabetes Minor Complexity
K60B	Diabetes Major Complexity
Procedure codes	
30511-02	Laparoscopic adjustable gastric banding
30511-04	Adjustable gastric banding
30511-09	Laparoscopic sleeve gastrectomy
30511-10	Sleeve gastrectomy

8.2.2 Key outcomes of interest and data analysis

Key outcomes estimated from the patient-level resource utilisation and aggregated cost data were: the length-of-stay and direct medical costs of the inpatient episodes-of-care for primary bariatric surgery in Tasmanian public hospitals for the pre-defined study population; the number and costs of all inpatient episodes-of-care before and after primary bariatric surgery for the pre-defined study population from 2007/08 to 2015/16 (also expressed as mean cost per patient and mean cost per episode-of-care); the number and costs of all episodes-of-care for 3 years before primary LAGB bariatric surgery and 3 years after primary LAGB bariatric surgery (on a year by year basis and totals), and calculated from the date of the primary surgical procedure, the pre- and postoperative total costs for both LAGB and SG; and the relative costs of the primary surgical procedure for LAGB versus SG in the Tasmanian public hospital system.

Subgroup and sensitivity analyses of the total inpatient costs for all surgical procedures for the study population included the investigation of cost outliers (defined as an episode-of-care > \$50,000). Subgroup analyses were conducted for patients with a reported history of diabetes or cardiovascular disease (including hypertensive diagnosis included in the admitted episode of care) sourced from patient diagnoses tables contained within the Patient Management System. Subgroup analyses were also conducted for patients with a BMI ≥ and < the median cut-point of the sample.

Surgical sequelae procedures' key outcomes of interest included the inpatient episode-of-care's length of stay and direct medical costs for surgical sequelae. Secondary surgical sequelae for the pre-defined study population included any LAGB device/implant-related procedures such as LAGB revisions or reversals, and LAGB port/reservoir-related procedures (e.g. port revision, port re-suturing, change of port, infection and/or wound or sinus debridement). Other surgical sequelae (i.e. directly related to the primary surgery) that generated an inpatient episode-of-care included hernia repair, cholecystectomy, complex gastro-intestinal procedures that were LAGB-related (e.g. leaks, bleeding and subsequent corrective surgery), any body-contouring surgery or body-lifting procedures [34] (e.g abdominoplasty or paniculectomy), and colonoscopy and gastroscopy. Length of stay and cost outliers for secondary surgical sequelae were identified and assumed as a length of stay of > 6 days per episode-of-care and a cost of ≥ \$25,000 per episode-of-care.

For surgical sequelae, individual patients could be represented more than once and this was included in the socio-demographic, clinical and cost analyses of the surgical sequelae and secondary procedures.

Summary data of socioeconomic characteristics were described as mean (standard deviation

(SD)) and median (inter-quartile range (IQR)) for continuous variables and frequencies for categorical variables. BMI was calculated as weight (kg)/height (m^2).

Costs were expressed in constant Australian dollars with 2014-15 as the reference year=100 (Appendix 2). There are a wide variety of price indexes (deflators) for the Australian health sector and these may be distinguished by the scope of the index or the technical manner in which the indexes are constructed and our studies costs were adjusted for inflation using the price index for Government Final Consumption Expenditure (GFCE) on hospitals and nursing homes index ([35]; Appendix 2). The GFCE on hospitals and nursing homes index is the index that most appropriately reflects the scope of the health servies being analysed in this study.

Statistical analyses were conducted with 'R' version 3.0.2.

$50,000, guided by this study's average cost per patient for an episode-of-care. For the analyses of primary and secondary bariatric surgery costs and length of stay, cost outliers were defined as > $25,000 for the primary and secondary bariatric surgical procedure and secondary surgical sequelae, based on the cost of primary bariatric surgery in the most recent Australian cost-utility study [36].

8.3 Results

8.3.1 Patient eligibility and characteristics

Figure 2 provides an outline of the flow of patients into the study.

One-hundred and five patients were included in the study. These patients underwent primary LAGB (n=89 patients) or SG (n=16 patients) bariatric surgery in the Tasmanian public hospital system. Detailed patient-level cost data were available for this study group of Tasmanian public hospital treated patients, but not for those contracted to private hospitals, nor patients treated elsewhere.

Clinical socio-demographic characteristics of the 105 included patients are reported in Table 2. For the LAGB bariatric surgery patient group, the mean (SD) age at the time of surgery was 47.9 (11.3) years and the SG bariatric surgery patient group was a decade older. Females represented almost three-quarters (74%) of the LAGB patient group and just over half (56%) of the SG patient group. The LAGB patient group's obesity classification and concomitant co-morbidity load revealed severe obesity (in the super obesity classification [37] BMI recorded for n=52 patients, mean (SD) BMI 50.2 (10.5) kg/m^2)) with multi-comorbidity (51% (diabetes), 53% (cardiovascular disease) and 61% (smoking)). Only one BMI reading was available for the SG patient group. The co-morbidity load for the SG patient group was higher with 69% of patients reporting a history of diabetes, 94% cardiovascular disease, and 88% reporting a history of smoking. Most of the primary bariatric surgery patients were retired, on a government pension, or unemployed (Table 2).

Twenty-seven of the 89 primary LAGB bariatric surgery patients (30%) underwent surgical sequelae LAGB-related surgery. Compared to the primary surgical group, this patient group had a higher mean age at the time of surgery sequelae (including secondary/revisional surgery) and an increased prevalence of cardiovascular disease. Diabetes prevalence was similar. The general trend of mean (SD) BMI was marginally higher 52.2 (9.2) kg/m^2 (Table 2). Only one of the 16 SG patients recorded a surgical sequelae event (outlined below).

Figure 2: Flow of patients into the study

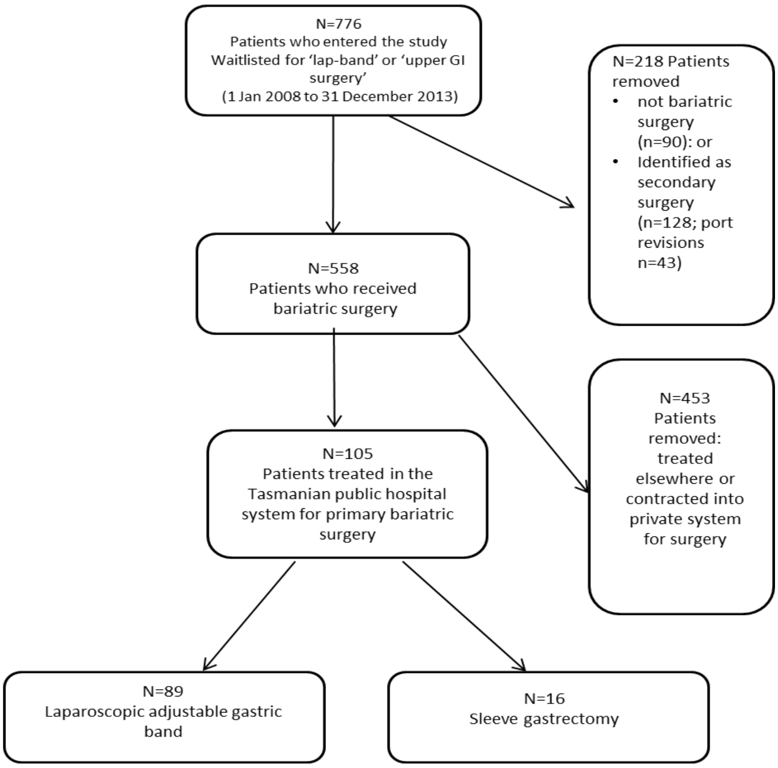


Table 2: Participant characteristics for patients who had primary laparoscopic adjustable gastric band (LAGB) surgery (n=89) and sleeve gastrectomy (SG) (n=16) surgery, and patients who had secondary LAGB-related surgery (n=27).

Patient characteristics (n=105)	Primary surgery		Secondary surgery
	LAGB (n=89)	Sleeve gastrectomy (n=16)	LAGB only (n=27)
Number of inpatient episodes of care	89	16	58
Age years (at surgery)*			
Mean (SD)	47.9 (11.3)	57.2 (8.1)	51.5 (10.7)**
Median (IQR)	47 (40 - 57) (at surgery)	59 (50 – 62.3) (at surgery)	48.5 (44.0 – 60.5) (at surgery)
Sex (n = x, %)			
Male	(n = 23, 26%)	(n = 7, 44 %)	(n= 7, 26%)
Female	(n = 66, 74%)	(n = 9, 56 %)	(n = 20, 74%),
Co-morbidity status (n=, %)			
Diabetes	(n = 45, 51 %)	(n = 11, 69 %)	(n = 12, 44%)
Cardiovascular disease	(n = 47, 53%)	(n = 15, 94 %)	(n = 19, %)
Smoker (reported history)	(n = 54, 61 %)	(n = 14, 88 %)	(n = 14, 52%)
Occupation status† (n=, %)			
Employed	(11, 12%)†	(1, 6%) ^	(3, 11%) †
Home Duties	(21, 24%)	(3, 19%)	(7, 26%)
Retired	(17, 19%)	(3, 19%)	(6, 22%)
Pensioner	(18, 20%)	(7, 44%)	(7, 26%)
Student	(0, 0%)	(0, 0%)	(1, 4%)
Unemployed	(5, 6%)	(0, 0%)	(1, 4%)
BMI Before surgery			
Mean (SD)	50.2 (10.5) ††	NA	52.2 (9.2)
Median (IQR)	48.6 (45.8 – 54.1)		52.7(48.8 – 58.1)
(Min, Max)	(32.4, 97.9)		(32.4, 66.4)

* Age in years at surgery identified at the inpatient episode for the primary surgical procedure;
** Age in years at surgery identified at the secondary surgical procedure (note that the same patient may be a different age for a different episode);
† Available data for occupational status reflected in the n=x; and
†† n = 52.

8.3.2 Public hospital utilisation and cost analyses

(i) Total episodes-of-care and costs for the study population

Table 3 describes the total costs of all inpatient episodes-of-care for the study population (n=105 patients) from the fiscal years 2007-08 to 2015-16 expressed in 2015 Australian dollars.

The total number of episodes-of-care for the study population over the 8 year time horizon was n=779 at a total cost to the Tasmanian (and to some extent Australian) healthcare system of $5,791,530. This total cost included the cost of the primary bariatric surgery and the surgical sequelae (including secondary and tertiary revisional surgery).

For the entire study population, (and excluding the episodes-of-care for the surgical procedures), the total number of inpatient episodes-of-care before surgery was n=278 at a cost of $1,529,211. After surgery (including the inpatient admissions costs for surgical sequelae, and excluding the costed inpatient episodes of care for the primary bariatric surgery (Table 3)) the number of episodes of care was n=397 at a cost of $2,792,670 (Table 3). The relative costs per episode of care for SG patients were lower than LAGB both before and after surgery (Table3). Additionally, for the LAGB group (n=89 patients) total costs for the n=692 episodes-of-care for the study population both pre- and postoperatively was $5,256,413. For the SG patient group (n=16 patients) total costs for the n=87 episodes-of-care both pre- and postoperatively was $535,117.

Regarding the the total costs for the bariatric surgical procedures themselves, the total cost for primary LAGB (n=89 patients) was $1,252,322 and for surgical sequelae (including secondary revisional surgery) $484,286, or an additional 39% of the cost of the primary procedure. The total cost for primary SG bariatric surgery was $217,327 (n=16 patients) (Table 3).

The relative costs per episode-of-care were $7,595 (LAGB) and $6,012 (SG), and the costs per patient were $59,069 (LAGB) and $33,444 (SG). Therefore, the LAGB patient's total episodes-of-care pre- and postoperative costs were almost twice the costs of SG patients (Table 3). One patient of the n=105 patients (LAGB) recorded a catastrophic event (major gastro-intestinal secondary surgery) with a 291 day stay at a cost of $362,724. A further nine cost outliers were identified and their costs ranged from $55,364 to $171,353 for an episode-of-care (Table 3). When all cost outliers were removed from the total cost's estimate, total costs reduced from $5,256,413 to $4,570,275 (Table 3). Sensitivity analyses also revelaed that the relative total costs for an episode-of-care reuced by almost $1,500 to $6,019 for LAGB patients and by over $500 to 5,407 for SG (Table 3).

Appendices 3A and 3B also provide the ICD-10-CM and AR-DRG coding for the total episodes-of-care identified from the administrative databases for the study cohort of n=105 people who received bariatric surgery.

Table 3: Total costs of all inpatient episodes of care for patients who were waitlisted (1 January 2008 to 31 December 2013), and then underwent primary bariatric surgery in the Tasmanian public hospital system over 8 years for the fiscal years 2007-08 to 2015-16 expressed in constant dollars (Reference case 2014-15=100), and sensitivity analyses (cost outliers removed).

	Totals	Totals (cost outliers removed)	Totals Before surgery††	Totals After surgery††
Global (n=105 patients)				
Number of episodes of Care	779†	768	278††	397††
Total costs ($)	5,791,530†*	4,570,275	1,529,211	2,792,670
Cost per episode	7,434	5,951	5,501	7,034
Costs per patient	55,157	43,526	14,563	26,597
LAGB (n=89)				
Episodes of Care (n=x)	692†	682	219††	384††
Total Costs ($)	5,256,413†*	4,105,239**	1,279,753	2,724,338
Cost per episode	7,595	6,019	5,843	7,094
Cost per patient	59,069	46,126	NA	NA
Total cost of primary surgery	1,252,322*			
Total cost of secondary surgery	484,268			
Sleeve gastrectomy (n=16)				
Episodes of Care (n=x)	87^	86**	59††	13††
Total Costs ($)	535,117^	465,036	249,458 ††	68,332 ††
Cost per episode	6,012	5,407	4,228	5,256
Cost per patient	33,444	29,064	15,591	4,271
Total cost of primary sleeve gastrectomy surgery (n=15)†	217,327	NA		

Notes:
Primary sleeve gastrectomy recorded from 2013-14.
LAGB=laparoscopic adjustable gastric band; LOS=length of stay (days); SG=sleeve gastrectomy includes *all* costs (including the cost of primary bariatric surgery).
* one major LAGB cost outlier of $362,724 included i.e. a multiple morbidity admission LOS 291 days;
**ten cost outliers removed for LAGB >$50,000 (namely, $ $50,761 primary LAGB surgery; $55,952 orthopaedic admission; $55,364 congestive cardiac failure admission LOS 44 days; $60,454 neurology admission LOS 7 days; $60,620 primary LAGB surgery; $91,593 multiple morbidity admission LOS 16 days; $110,548 brain tumour admission LOS 42 days; $131,805 surgical sequelae from primary LAGB surgery; $171,353 multiple morbidity LOS 43 days; and 362,724 multiple morbidity admission LOS 291 days);
† costs available for n=15 sleeve gastrectomy (not available for one primary surgery in 2016-2017)
†† totals before and after surgery do not include the cost of the primary surgical procedure, however, do include the cost of the secondary and tertiary surgical sequelae procedures after surgery. Note that SG (n=15) for costed primary surgery.

(ii) Year-on-year public hospital utilisation and costs

Table 4 provides analyses of all inpatient episodes-of-care and costs pre- and postoperatively for the LAGB surgical group (n=89 patients) 3 years before (defined as -3 years from the date of the primary procedure, -2 years, -1 year) and for the 3 years after surgery (described as +1 year from the date of the primary procedure, +2 years and +3 years).

Table 4 particularly highlights that the number of episodes-of-care and costs increased from -

3 years to -1 year before surgery and for the 2 years after surgery, and then recorded a decrease at year +3 after surgery. More specifically, episodes-of-care: -3 year, 30 episodes-of-care; -2 year, 60 episodes-of-care; -1 year, 82 episodes-of-care; +1 year, 72 episodes-of-care; +2 year, 88 episodes-of-care; +3 year, 34 episodes-of-care; and costs per episode-of-care: -3 year $5,431, -2 year $4,697, -1 year $5,301 and +1 year $7,431; +2 year, $12,587 and +3 year $3,612. Interestingly, this result revealed that the number of inpatient episodes-of-care reduced from 82 in the -1 year before surgery to 34 episodes-of-care +3 years after surgery, at an average cost of $5,301 and $3,612 respectively. The table also revealed that the number of episodes-of-care and total and average costs maximised at +2 year after surgery.

The subgroup analyses presented in Table 4 revealed that the general trend of a decrease of costs per episode-of-care at year +3 after surgery was lower than for the entire study population. To illustrate, for patients with cardiovascular disease and diabetes, the difference from year -1 before surgery to year +3 after surgery was $3,350 and $2,752 respectively, compared to $1,689 for the entire study population. The total cost and episodes-of-care maximised at year +2 after surgery for the entire cohort and people with cardiovascular disease. Interestingly, for people with diabetes average costs maximised before surgery and a decrease in average costs was revealed from the +1 year after surgery (compared to year +3 for the entire cohort and for people with cardiovascular disease).

Table 4: Total costs and inpatient episodes of care for patients who were waitlisted (1 January 2008 to 31 December 2013), and then underwent primary bariatric surgery in the Tasmanian public hospital system expressed in constant dollars (Reference case 2014-15=100) for the 3 years before and after surgery, and sensitivity (cost outliers omitted) and subgroup analyses (patients with diabetes and cardiovascular disease).

Laparoscopic adjustable gastric band (n=89)	**Before Surgery**				**After Surgery**			
	- 3 years	-2 years	-1 years	Total/average (before surgery)	+1 year	+2 years	+3 years	Total/average (after surgery)
Episodes of Care	38	60	82	180	72	88	34	194
Total Costs	206,369	281,796	434,710	922,875	535,296	1,107,691	122,820	1,765,807
Average cost per EoC	5,431	4,697	5,301	5,143 (average)	7,435	12,587	3,612	7,878 (average)
Sensitivity analyses Cost outliers removed								
Episodes of Care	37	60	81	178	72	85	34	191
Total costs	145,915	281,796	343,117	770,828	535,296	502,614	122,820	1,160,730
Average costs per EoC	3,944	4,697	4,236	4,292	7,435	5,913	3,612	5,653
Total cost outliers removed	60,454*	No cost outliers	91,593**	152,047	No cost outliers	605,077***	No cost outliers	605,077
Subgroup analysis Patients with diabetes (n=45)								
Episodes of Care	15	19	26	60	36	49	20	105
Total Costs	49,453	125,651	181,580	356,684	201,969	251,220	84,641	537,830
Average cost per EoC	3,297	6,613	6,984	5,631	5,610	5,127	4,232	4,990
Cost outliers removed	No cost outliers	No cost outliers	No cost outliers		No cost outliers	No cost outliers	No cost outliers	
Subgroup analysis Patients with CVD (n=47)								
Episodes of Care	23	45	55	123	56	57	23	136
Total Costs	155,545	237,860	375,062	768,467	447,234	475,654	79,794	1,002,682
Average cost per EoC	6,762	5,286	6,819	6,289	7,986	8,344	3,469	6,600
Cost outliers removed	1*	No cost outliers	1**	2	No cost outliers	1	No cost outliers	1
Episodes of care	22	45	54	121	56	56	23	135
Total costs	95,091	237,860	283,469	616,420	447,234	343,805	79,794	870,833
Average cost per EoC	4,322	5,286	5,249	4,952	7,986	6,140	3,469	5,865

*cost outlier >$50,000 namely, $60,454 neurology
** cost outlier >$50,000 namely $91,593 multiple medical issues not surgical sequelae
*** cost outlier >$50,000 namely $362,724 multiple issues LOS 291 days; 110,548 brain tumour LOS 42 days; $131,805 bariatric surgery cost outlier surgical sequelae.
EoC=episode-of-care

(iii) Primary bariatric surgery

Table 5 describes total hospital utilisation and summary inpatient episode-of-care costs and subgroup analyses (diabetes and BMI) for primary LAGB and primary SG bariatric surgery. Figures 3A and 3B provide the frequency distributions for inpatient LAGB episode-of-care costs, and episode-of-care costs per day.

The mean (SD) length of stay for SG was 1.6 days longer than LAGB (LAGB: 2.4 (3.6) days). When length of stay outliers were omitted for LAGB sensitivity analyses (n=6; range 6 to 30 days) this reduced to 1.7 (0.9) days per episode-of-care for primary LAGB bariatric surgery (Table 5).

Mean (SD) costs for an inpatient episode-of-care for primary LAGB and SG surgeries were $14,071 (8,797) and $14,448 (5,678), respectively. The mean costs per day for SG were half the cost for LAGB (Table 5). When cost outliers were omitted for the LAGB primary surgery sensitivity analyses (i.e. n=6; range $26,758 to $60,620), the inpatient cost per episode-of-care for primary surgery reduced to $12,120 (4,022). There were no reported cost outliers for SG primary bariatric surgery (Table 5, Table 3, Figure 2A). The base case costs per day for an episode-of-care revealed that the mean (SD) costs per day for SG were half the cost for LAGB (Table 5).

Subgroup analyses for the LAGB primary surgery group revealed that most cost outliers were people with a reported history of diabetes (n=45) (Tables 3, 5, Figures 3C and 3D).

Overall, LAGB subgroup analyses for patients with or without diabetes revealed that the mean cost per inpatient episode-of-care for surgically-treating people with diabetes was $3,660 higher ($p$=0.02) than for people without diabetes. When cost outliers were omitted from both samples (study participants with a history of diabetes n=5 and study participants without a history of diabetes n=1) this difference reduced to only $1,660 (*p*=0.06) (Table 5). Inpatient length of stay analyses revealed similar trends. Table 4 also revealed that the average cost per episode-of-care for people with diabetes decreased substantially from 1 year before surgery to 3 years after surgery, and that the total cost was reduced by almost half.

The SG subgroup with a reported history of diabetes (n=11) revealed similar costs to the LAGB subgroup with diabetes (SG mean (SD); $15,300 ($6,246)) (Table 5). Nevertheless, Table 4 showed that costs and episodes-of-care for people with diabetes decreased from +1 year after surgery (compared to year +3 for the entire cohort and for people with cardiovascular disease).

Subgroup analyses of people with a BMI classified above and below the median cut-point of 48.6 kg/m for LAGB primary bariatric surgery, revealed that the mean cost per inpatient episode-of-care for the primary surgical procedure for people with a BMI > 48.6 kg/m^2 (n=26) was $4,770 higher than for people with a BMI ≤ 48.6 kg/m^2 (n=26). This result was not statistically significant. Similar trends were revealed for length of stay (Table 5).

Table 5: Inpatient episode-of-care length of stay (days) and public hospital activity based funding costs expressed in constant dollars (Reference case: 2014-15 = 100) for patients who underwent primary laparoscopic adjustable gastric band (LAGB) (n=89) and sleeve gastrectomy (SG) (n=16) bariatric surgery in the Tasmanian public hospital system, and subgroup analyses.

Primary Surgery (n=105)	Episode-of-care for primary surgery (n=x)	Length of stay Mean (SD)	Length of stay (sensitivity analyses) Mean (SD)	Cost of episode-of-care Mean (SD) Median (IQR) Min, Max	Cost of episode-of-care (sensitivity analysis) Mean (SD) Median (IQR) Min, Max	Cost of episode-of-care per day Mean (SD) Median (IQR) Min, Max
LAGB (n=89)						
Entire cohort	89	(n=89) 2.4 (3.6)	(n=83) 1.7 (0.9)ƚ	(n = 89) 14,071 (8,797) 11,830 (9,814 – 14,870) (5,142, 60,620)	(n=83)* 12,120 (4,022) 11,630 (9,595 – 14,040) (5,142; 22,940)	(n=89) 8,709 (6,093) 7,408 (5,333 – 10,700) (1,065; 50,760)
Subgroup analyses						
Diabetes	45	3.1 (4.8)	(n=40)** 1.8 (0.8)	(n = 45) 15,880 (10,100) 12,580 (10,380 – 18,050) (5,467; 60,620)	(n=40) 12,980 (4,431) 12,180 (9,991 – 15,020)	NA
ToS WR		*p* = 0.01	*p = 0.06*	*p* = 0.02	p = 0.07	
No diabetes	44	1.7 (1.3)	(n=43)*** 1.6 (0.9)	(n=44) 12,220 (6,860) 10,800 (9,516 – 12,530) (5142; 50,760)	(n=43) 11,320 (3,463) 10,700 (9,514 – 12,390) (5,142; 21,670)	NA
BMI (high) ≥ 48.6	26	3.7 (6.1)	NA	16,620 (13,552) 12,300 (10,400 – 15,250) (5142; 60,620)	NA	NA
ToS WR		*p* = 0.24	NA	*p* = 0.15	NA	
BMI (low) < 48.6	26	1.9 (1.3)		11,960 (6,227) 10,920 (8,774 – 11,980) (5,323; 37,430)		
Sleeve Gastrectomy (n=16)						
Entire cohort	16	4.0 (1.1)	3.8 (1.1)	14, 448 (5,678)‡ 12, 789 (10,581 - 18,040) (6,312; 25,172) *p* = 0.80	NA	3,878 (6,124) 3,197 (2,969 – 4,410) (2,104; 7,737)
Diabetes	11	NA	3.9 (1.3)ƚƚƚ	15,300 (6,246) 14,010 (8,749 – 20,670) (8,684; 25,170)	NA	NA

LAGB = laparoscopic adjustable gastric band; SG = sleeve gastrectomy; LoS = length of stay; ToS WR = test of significance Wilkoxon rank sum test; *Reference case 2014-15 = 100; ‡ cost data for primary sleeve gastrectomy available for (n=15) patients (also see Table 3). Cost outliers removed > $25,000. ** n=5 LOS outliers removed in diabetes subgroup (range 6 to 30 days); *** n=1 outlier removed in not diabetes subgroup 8 days; ƚƚƚ (n=10).

Figure 3A and 3B: Frequency distribution of an episode-of-care of inpatient costs expressed in constant dollars (Reference 2014-15=100) for all patients (n=89) who received laparoscopic adjustable gastric band surgery (2A) and cost/day for an episode-of-care (2B).

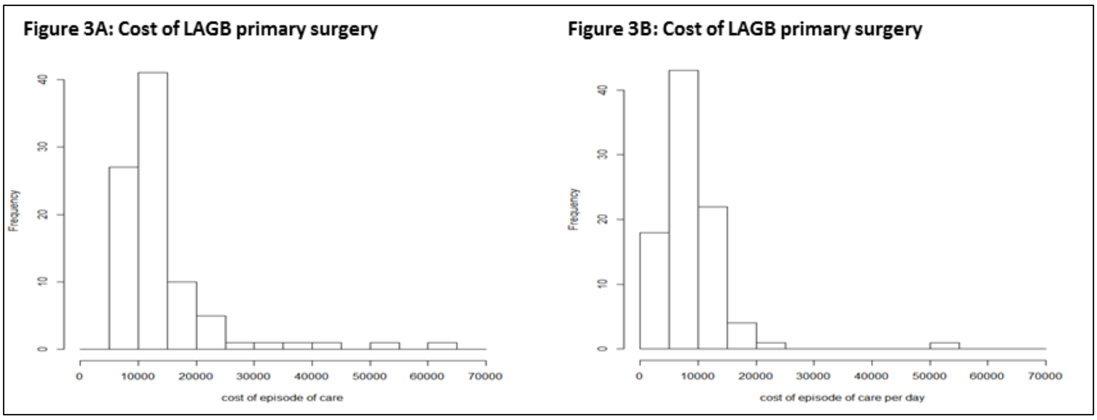
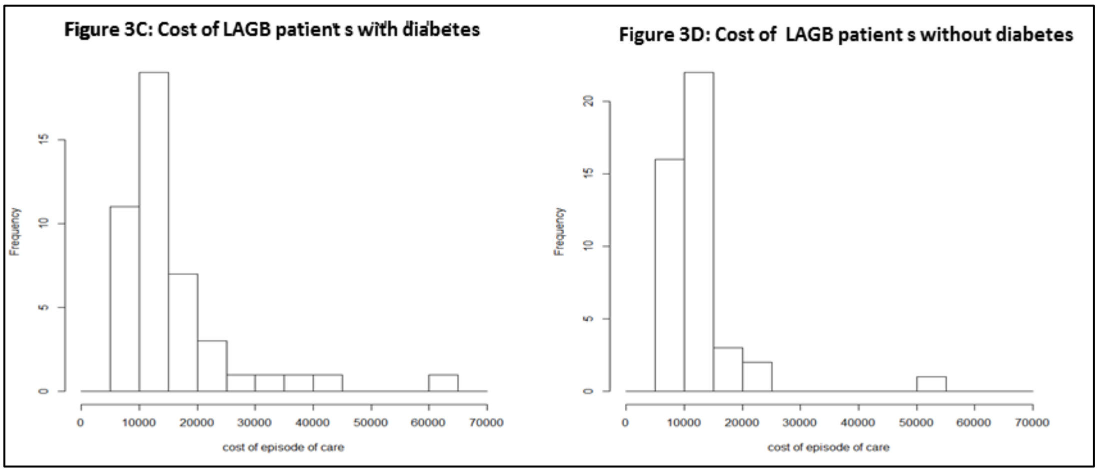


Figure 3C and 3D: Frequency distribution of inpatient episode-of-care costs expressed in constant dollar (Reference 2014-15=100) for all patients with diabetes (n=46) and without diabetes (n=45) who underwent laparoscopic adjustable gastric band surgery in the Tasmanian public hospital system.



(iv) Surgical sequelae: LAGB and SG

Table 6 describes the inpatient hospital utilisation and direct medical costs of LAGB-related surgical sequelae and secondary LAGB surgery. The classifications of secondary/tertiary LAGB surgery for analyses included LAGB device/implant-related procedures (e.g. revision or reversals of the LAGB-system, change of tubing, re-suturing of port, flipped port, change of port, wound or sinus debridement related to an infected port), and surgical sequelae of colonoscopy/gastroscopy, hernia repair, cholecystectomy, and body-contouring surgery.

Twenty-seven patients (30%) recorded a LAGB surgical sequelae (including secondary/tertiary revisional surgery) and (n=58) associated inpatient episodes-of-care. Of these (n=27) patients, 8 patients required ≥ 3 secondary surgical procedures and an associated inpatient episode-of-care. Over half of the surgical sequelae procedures were secondary surgery LAGB-device/implant related (n=33 of the n=58 episodes-of-care; 57%), and most of these procedures were LAGB port/reservoir-related surgical procedures (Table 6).

Sixteen patients required n=33 episodes-of-care for LAGB device-related procedures, and 12 patients required 27 episodes-of-care for LAGB port-related procedures. The remaining device-related procedures were LAGB revisions or reversals (n=6). Colonoscopy and gastroscopy accounted for 10 of the (n=58) episodes-of-care of the surgical sequelae procedures. There were only two major LAGB-related secondary gastro-intestinal surgical procedures, related to two patients. Only 1 of these procedures could be classified as a post-operative catastrophic event and was a major cost outlier of the cohort (Table 6).

The mean (SD) inpatient length of stay and costs for the total episodes-of-care for LAGB-related surgical sequelae were 3.5 (6.6) days and $9,495 (18,585) respectively. Removal of length of stay and cost outliers for sensitivity analyses revealed a substantial reduction in both length of stay and costs to 1.8 (1.5) days and $6,158 (4,693) per inpatient episode-of-care (Table 6).

Mean (SD) LAGB port/reservoir-related costs per inpatient episode-of-care was $5,096 (3,711). Revisions or reversals of the LAGB device (not specifically described or classified as a device/port-related procedure) accounted for 12% of the total episodes-of-care, and the mean (SD) costs were $11,310 (6,181). Colonoscopy and gastroscopy accounted for 17% of the episodes-of-care and mean (SD) costs were $2,430 (1,062) (Table 6). Body-contouring surgery (abdominoplasty and paniculectomy) was provided to one patient at a length of stay of 4 days (cost data not available as procedure undertaken in current fiscal year) (Table 6).

Of the 16 primary SG procedures, 14 procedures were performed in 2015 and 2016. There were 13 episodes-of-care recorded after the primary SG procedures and one of these procedures could be attributed as surgical sequelae of the primary sleeve gastrectomy procedure. This inpatient episode-of-care was a laparoscopic cholecystectomy performed 10 months after the SG procedure at a cost of $7,467.

Table 6: Length of stay and costs for secondary and tertiary surgery for medical sequelae after laparoscopic adjustable gastric band (LAGB) surgery, and sensitivity and subgroup analyses.

LAGB secondary surgery (n=27)	Episodes-of-care (n=x)	Patients (n=x)	Length of stay (days) Mean (SD) Median (IQR)	Costs Mean (SD) Median (IQR) (Min, Max)
Total	51 (cost)† 58(LoS)	27	3.5 (6.6) 1 (1 – 3.8) (1; 46)	9,495 (18,585) †† 4791(3201 – 10,600) (149; 131,800)
Sensitivity analysis 1* (cost and LoS outliers removed)	50 (cost) 57 (LoS)	27	2.7 (3.3) 1 (1 – 3) (1; 20)	7,049 (6,408) 4,756 (3,195 – 10,190) (149; 31,870)
Sensitivity analysis 2** (cost and LoS outliers removed)	48 (cost) 51 (LoS)	27	1.8 (1.5) 1 (1 – 2) (1; 6)	6,158 (4,693) 4,618 (2,976 – 9,318) (149; 18,260)
Subgroup analyses				
Device-related (including port-related)	33	16	2.2 (2.4) 1 (1 – 2) (1; 11)	6,031 (4,533) 4,721 (3,260 – 9,046) (149; 15,660) Costs 29
Port-related	27	12	1.8 (2.3) 1 (1 – 1) (1; 11)	5,096 (3,711) 4,444 (3,248 – 6,061) (149; 14,960) Costs 25
Revision or reversal	6		3.5 (2.1) 3.5 (2 – 5) (1 – 6)	11,310 (6181) 13,560 (11,850 – 14,920) (560; 15,660)
Colonoscopy/ Gastroscopy	10	9	1 day	2,430 (1,062) 2,199 (1,664 – 2,976) (1,326; 4,133)
Cholecystectomy	4	4	3 (1.2)	9,609 (4,076)* 10,210 (7,738 – 11,780) (5,264; 13,350)
Hernia repair	4	4	3.3 (3.9) 1.5 (1 – 3.8) (1, 9)	9,928 (8,537) 6,522 (5,136 – 11,310) (4,111; 22,650)
Body contouring surgery	1	1	4	NA

LoS, length of stay
† n=51 costs i.e. n=7 costs not available
†† note that totals costs for the n = 51 episodes-of-care were $484,268 ((Reference case: 2014-15 = 100)
* Sensitivity analyses 1: one major cost and length of stay outlier for major and complicated gastro-intestinal surgery length of stay 46 days (including an ICU admission of 3,199 minutes) and cost $131,805;
** Sensitivity analyses 2: length of stay outliers > 6 days (n = 6) and cost outliers ≥ $25,000 (n = 2; $131,805 and $31,871);
*** (n=3) costs

8.4 Discussion

8.4.1 The costs of obesity and bariatric surgery in Tasmania

Our study provided much needed information regarding the inpatient episodes-of-care, resource use and costs of obesity and bariatric surgery in the Tasmanian public hospital system. We extracted data on an individual patient basis to track the primary Activity Based Funding episodes-of-care and the costs attributed to each patient pathway before and after primary bariatric surgery.

We found that total costs of public hospital inpatient care to the Tasmanian public healthcare system for the 105 patients waitlisted for, and who subsequently received bariatric surgery in the Tasmanian public healthcare system over an 8 year time horizon was almost $5.8 million dollars, of which $1.7 million dollars was for primary bariatric surgery procedures.

Another key finding was that the average cost of providing primary bariatric surgery in the Tasmanian public hospital system is lower than the most recent Australian estimate, which was derived from a sample of Queensland data and then extrapolated in a cost-effectiveness model The base case scenario of a severely obese 30 year old female with no co-morbidity was estimated to cost $24,167 for a primary AGB and $52,440 for a SG [24]. We also found that our average cost of providing primary bariatric surgery in the Tasmanian public hospital system is lower than recent comparable international estimates [1]. For example, recent Canadian estimates for bariatric surgery are $15,000 to $20,000 Canadian dollars for the primary surgery [1].

Other findings included that cost outliers are mostly patients with a reported history of diabetes, and that for LAGB primary surgery device/implant-related medical sequelae accounted for half of the secondary and tertiary surgery. From a patient journey/pathway perspective, we also found that device-related procedures were concentrated to a subgroup of patients.

Importantly, we also found that for people with diabetes the costs for inpatient public hospital care from a total cost and cost per episode-of-care perspective, that costs were substantially reduced 3 years after surgery compared to 1 year before surgery.

Another interesting finding from our subgroup analysis was that the average cost for an episode-of-care decreased for people with diabetes from the first year after surgery.

A recent AIHW study estimated the cost of primary bariatric surgery by adopting a narrower cost-base (Australian Medicare-linked data) than our study or the recent Australian cost-utility study [5]. The AIHW report reported that the costs of primary bariatric surgery were marginally lower than our base case analyses. Nevertheless, this report does not include the broader costs captured in our study using ABF data linked with patient records.

Overall, our findings suggest that bariatric surgery in the Tasmanian public hospital system may be an attractive value-based option in the longer term: bariatric surgery realised health benefits (reduced inpatient episodes-of-care) and reduced costs at year 3 postoperatively. One year preoperatively the study population recorded the highest number of inpatient episodes-of-care and costs suggesting that the severely obese study population with multi-morbidity was experiencing substantially reduced health 1 year before surgery. We also found that the cost of bariatric surgical sequelae (including secondary and tertiary revisional surgery) maximised at year 2. The maximisation of inpatient-episodes-of-care and costs at year 2 suggests that postoperative care should be ongoing during this critical time horizon and could potentially mitigate some of these inpatient costs.

8.4.2 Surgical sequelae (including secondary/tertiary surgery)

Our investigation of patient-level data regarding surgical sequelae after primary LAGB surgery is novel. We tracked each publicly-treated LAGB and SG patient's individual inpatient episode-of-care and cost pathway to provide our project partners with a comprehensive understanding of the patient pathway, and prevalence of surgical sequelae, and secondary and tertiary surgery resource use and costs.

Importantly, our study found that over half of the costs of complications and reoperations for publicly-treated LAGB patients were device-related and that these episodes-of-care and costs were mostly LAGB port/reservoir-related and concentrated to a further subgroup of patients. Nevertheless, the overall costs of bariatric surgery (including the total costs of reoperations and complications) for our older and sicker cohort of bariatric surgery patients were less than the direct medical costs reported in the most recent Australian cost-utility study.

We also found that for sleeve gastrectomy, only 1 of 16 inpatient episodes-of-care could be attributed to surgical sequelae.

A recent comprehensive systematic review regarding the health economic evaluation of bariatric surgery, found that one-third of the 77 included studies either ignored the costs and/or consequences of complications and reoperations, or for the studies that accounted for reoperations and complications commonly only assumed short-term events, considered an incomplete list of complications or assumed relatively low probabilities of adverse events occurring. The review also found that the longer-term costs of bariatric surgery have therefore probably been underestimated, and the value for money for bariatric surgery subsequently overestimated. Additionally, the most recent Australian cost-utility study estimated the prevalence of surgical sequelae and secondary surgery from the literature (notwithstanding estimating the surgical costs from an administrative database).

In direct comparison, our study suggests that the most recent health economics studies have underestimated the prevalence and real costs of surgical sequelae and secondary/tertiary bariatric surgery.

8.4.3 Resource allocation: type of surgery and patient prioritisation

Contemporary debate regarding the provision of bariatric surgery has, to a certain degree, shifted beyond the cost per QALY health economic metric to the economic barriers-to-entry in public healthcare systems, and the associated issue of supply not meeting ever-increasing demand for publicly-provided bariatric surgery [13, 38].

Other authors have called for a reconsideration of the use and role of adjustable gastric band surgery (compared to other procedures such as SG), particularly for Medicare beneficiaries in the United States [39-41]. A recent key epidemiological study that investigated reoperations and Medicare (United States) expenditures after LAGB surgery found that device-related reoperation was common, costly and varied widely across hospital referral regions [42]. On the other hand, it has been suggested that no single bariatric procedure is appropriate for all patients, and that the regional variation in outcomes observed is important [40].

Given our study's reported rates (and costs) of secondary/tertiary LAGB device-related surgery, policy-makers should reconsider the type of surgery provided to certain patient groups to mitigate LAGB device-related issues.

A common theme that has emerged from a review of the health economics reporting of bariatric surgery is that it is highly cost-effective (and even cost-saving) for severely obese patients with type 2 diabetes [1]. Our subgroup analyses revealed that half of our severely obese cohort had a history of diabetes, and that the cost of providing them with primary surgical procedure was only marginally higher than for people without diabetes. More importantly, our subgroup analyses for people with diabetes also found that total costs of publicly-funded inpatient care were substantially reduced 3 years after bariatric surgery.

Our previously published work has also found that long-waiting public hospital system bariatric surgery patients should not be 'written-off' by healthcare planners – they can still realise significant improvements in health-related quality-of-life outcomes when ultimately treated, and this should be factored into patient prioritisation decisions [43]. Our previously published work also suggested that addressing this issue given the large gap between the demand for and supply of publicly funded bariatric surgery in many countries, would require significant commitment and investment [43].

8.4.4 Strategic research alliance in an applied health economics study

Our study harnessed the comparative advantages of a self-assembled strategic alliance that comprised heterogeneous human capital. The team identified key gaps for the state government partner regarding the resource use and costs of publicly-provided bariatric surgery including a comparison between LAGB and SG surgery. Additionally, this study has enabled university researchers to build on a collaborative and productive relationship with our health partner.

8.4.5 Limitations and Strengths

The main limitation of our study was the sample size for SG. Nevertheless, our Tasmanian State Government partner indicated that this subgroup was important and that we should track each patient journey for this group. We recommend that a larger conformatory study of disaggregated costs for later years (that is from 2013-14 onwards) be conducted given that SG as a treatment option in the Tasmanian public hospital system from 2013 may have increased.

A further limitation was that it focused on the inpatient hospitalisation and direct medical costs (compared to, for example, primary care). On the other hand, this focus was also a key strength of our paper because we provided our policy decision-makers with important information about the study population that was previously unknown. The large sample size of bariatric surgery patients and their associated before and after surgery episodes-of-care that were individually tracked for a long time horizon was a strength. Sufficient data to enable robust sensitivity and subgroup analyses over a long timeframe was also a strength. A final limitation is about our assumption that secondary surgical sequelae includes colonoscopies. On the other hand, there were only a few colonoscopies identified in the sample (combined gastroscopy and colonoscopy 10 episodes-of-care) and a proportion of this small sample would be directly related to LAGB surgery. We also suggest that a larger confirmatory study investigate the rate of colonoscopy and gastroscopy for the Tasmanian public hospital system.

8.5 Conclusions

The costs of providing bariatric surgery in Tasmania are lower than comparable national and international published estimates, even after Tasmanian costs for surgical sequelae and secondary/tertiary surgery are included. A robust cost-effectiveness study could be the subject of further research for the retrospective cohort and our planned prospective cohort.

Targeting appropriately prioritised patients with SG in preference to LAGB surgery in Tasmania would mitigate LAGB implant-related costs.

Patients with diabetes and cardiovascular disease incur lower costs in the longer term after bariatric surgery.

This study and our earlier health-related quality of life work provides the building blocks for our project team to conduct a robust and real world cost-effectiveness analysis for our DHHS project partner. We also recommend that a larger confirmatory ABF cost study (that investigates disaggregated costs) about SG versus LAGB (and other forms of bariatric surgery that could now be offered) in the Tasmanian public hospital system from 2013 onwards be conducted.

8.6 References

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Appendix 8.1: Consolidated Health Economic Evaluation Reporting Standards (CHEERS) 24 item checklist

Section/Item	Item	Recommendation
Title and Abstract		
Title	1	Identify the study as an economic evaluation or use more specific terms such as "cost-effectiveness analysis", and describe the interventions compared.
Abstract	2	Provide a structured summary of objectives, perspective, setting, methods (including study design and inputs), results (including base case and uncertainty analyses), and conclusions.
Introduction		
Background and objectives	3	Provide an explicit statement of the broader context for the study. Present the study question and its relevance for health policy or practice decisions.
Methods		
Target population and subgroups	4	Describe characteristics of the base case population and subgroups analysed, including why they were chosen.
Setting and locations	5	State relevant aspects of the system(s) in which the decision(s) need(s) to be made.
Study perspective	6	Describe the perspective of the study and relate this to the costs being evaluated.
Comparators	7	Describe the interventions or strategies being compared and state why they were chosen.
Time horizon	8	State the time horizon(s) over which costs and consequences are being evaluated and say why appropriate.
Discount rate	9	Report the choice of discount rate(s) used for costs and outcomes and say why appropriate.
Choice of health outcomes	10	Describe what outcomes were used as the measure(s) of benefit in the evaluation and their relevance for the type of analysis performed.
Measurement of effectiveness	11a	Single study-based estimates: Describe fully the design features of the single effectiveness study and why the single study was a sufficient source of clinical effectiveness data.
	11b	Synthesis-based estimates: Describe fully the methods used for identification of included studies and synthesis of clinical effectiveness data.
Measurement and valuation of preference based outcomes	12	If applicable, describe the population and methods used to elicit preferences for outcomes.
Estimating resources and costs	13a	Single study-based economic evaluation: Describe approaches used to estimate resource use associated with the alternative interventions. Describe primary or secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs.
	13b	Model-based economic evaluation: Describe approaches and data sources used to estimate resource use associated with model health states. Describe primary or secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs.
Currency, price date, and conversion	14	Report the dates of the estimated resource quantities and unit costs. Describe methods for adjusting estimated unit costs to the year of reported costs if necessary. Describe methods for converting costs into a common currency base and the exchange rate.
Choice of model	15	Describe and give reasons for the specific type of decision-analytical model used. Providing a figure to show model structure is strongly recommended.
Assumptions	16	Describe all structural or other assumptions underpinning the decision-analytical model
Analytical methods	17	Describe all analytical methods supporting the evaluation. This could include methods for dealing with skewed, missing, or censored data; extrapolation methods; methods for pooling data; approaches to validate or make adjustments (such as half cycle corrections) to a model; and methods for handling population heterogeneity and uncertainty.
Results		
Study parameters	18	Report the values, ranges, references, and, if used, probability distributions for all parameters. Report reasons or sources for distributions used to represent uncertainty where appropriate. Providing a table to show the input values is strongly recommended.
Incremental costs and outcomes	19	For each intervention, report mean values for the main categories of estimated costs and outcomes of interest, as well as mean differences between the comparator groups. If applicable, report incremental cost-effectiveness ratios.
Characterising uncertainty	20a	Single study-based economic evaluation: Describe the effects of sampling uncertainty for the estimated incremental cost and incremental effectiveness parameters, together with the impact of methodological assumptions (such as discount rate, study perspective).
	20b	Model-based economic evaluation: Describe the effects on the results of uncertainty for all input parameters, and uncertainty related to the structure of the model and assumptions.
Characterising heterogeneity	21	If applicable, report differences in costs, outcomes, or cost-effectiveness that can be explained by variations between subgroups of patients with different baseline characteristics or other observed variability in effects that are not reducible by more information.
Discussion		
Study findings, limitations, generalisability, and current knowledge	22	Summarise key study findings and describe how they support the conclusions reached. Discuss limitations and the generalisability of the findings and how the findings fit with current knowledge.
Other		
Source of funding	23	Describe how the study was funded and the role of the funder in the identification, design, conduct, and reporting of the analysis. Describe other nonmonetary sources of support.
Conflict of interest	24	Describe any potential for conflict of interest of study contributors in accordance with journal policy. In the absence of a journal policy, we recommend authors comply with International Committee of Medical Journal Editors recommendations.

Appendix 8.2A: The principal and additional diagnoses for ICD-10-CM codes for our study population (n=105) of people who received primary and secondary laparoscopic adjustable gastric band surgery in the Tasmanian public hospital system.

Principal and secondary diagnosis ICD-10-CM	Description
B95.6	Staphylococcus aureus
D64.9	Anaemia unspecified
E65	Localized adiposity
E66.8	Other obesity
E66.9	Obesity, unspecified
E10.61	Type 1 diabetes mellitus
E10.64	Type 1 diabetes mellitus
E10.74	Type 1 diabetes mellitus
E11.21	Type 2 diabetes mellitus
E11.22	Type 2 diabetes mellitus
E11.31	Type 2 diabetes mellitus
E11.4	Type 2 diabetes mellitus
E11.65	Type 2 diabetes mellitus
E11.71	Type 2 diabetes mellitus
E11.72	Type 2 diabetes mellitus
E87.6	Hypokalaemia
G47.32	High altitude periodic breathing
G62.9	Polyneuropathy, unspecified
H35.0	Background retinopathy
K31.88	Diseases of the oesophagus, duodenum and stomach
K42.9	Umbilical hernia without obstruction or gangrene
K43.2	Incisional hernia
K43.9	Ventral hernia
K44.9	Diaphragmatic hernia
K55.8	Other vascular disorders of intestine
K56.5	Internal adhesions with obstruction
K66.0	Peritoneal adhesions
K80.1	Calculus of gallbladder with other cholycystitis
K92.2	Gastrointestinal haemorrhage, unspecified
I10.0	Essential (primary) hypertension
I20.0	Incisional hernia without obstruction or gangrene
I95.5	Hypotension
I97.8	Other intraoperative and post procedural complications and disorders
I99.59	Chronic embolism and thrombosis of other specified deep vein of lower extremity
M79.58	Residual foreign body in soft tissue, other site
M79.61	Achilles tendonitis, right leg
M79.62	Pain in upper arm
N18.2	Chronic kidney disease
N18.9	Chronic kidney disease
N99.0	Post procedural (acute)(chronic) kidney failure.
R00.0	Tachycardia, unspecified
R00.1	Bradycardia unspecified
R07.4	Chest pain, unspecified
R10.4	Other and unspecified abdominal pain
R19.5	Other faecal abnormalities
R51.0	Headache
R52.2	Headache
S35.2	Injury of celiac or mesenteric artery and branches
S36.52	Contusion of colon
T43.0	Poisoning by, adverse effect of and under dosing of tricyclic and tetracyclic antidepressants
T81.0	Haemorrhage or haematoma complicating a procedure, not elsewhere classified
T81.1	Post procedural shock
T81.2	Accidental puncture and laceration during a procedure, not elsewhere classified
T81.2	Post-procedural shock
T81.4	Infection following a procedure
T85.5	Complications of foreign body accidentally left in body following procedure
T85.6	Mechanical complication of other specified internal and external prosthetic devices
T85.78	Infection and inflammatory reaction to other internal prosthetic devices, implants and grafts
U79.3	Depression
U82.3	Hypertension
U86.2	Arthritis and osteoarthritis
Y60.0	Unintentional cut, puncture, perforation or haemorrhage during surgical and medical care
Y60.8	Unintentional cut, puncture, perforation or haemorrhage
Y83.1	Surgical operation with implant of artificial internal device as the cause of abnormal reaction of the patient, or of later complication, without mention of misadventure at the time of the procedure
Y83.8	Other surgical procedures as the cause of abnormal reaction of the patient, or of later complication, without mention of misadventure at the time of the procedure
Y92.22	Religious institution as the place of occurrence of the external cause
Z41.1	Encounter for cosmetic surgery
Z72.0	Tobacco use
Z80.0	Family history of
Z86.43	Personal history of benign neoplasm
Z92.21	Personal history of antineoplastic chemotherapy
Z92.22	Personal history of monoclonal drug therapy
Z95.5	Presence of coronary angioplasty and graft
Z96.8	Presence of other specified functional implants

Appendix 8.2B: Australian Refined Diagnostic Related Groups for people who received primary and secondary laparoscopic adjustable gastric band primary and secondary surgery in the Tasmanian public hospital system (n=105).

AR-DRG	Description
F21B	Other Circulatory System GIs, Intermediate Complexity*
G02A	Major Small and Large Bowel Procedures, Major Complexity*
G02B	Major Small and Large Bowel Procedures, Intermediate Complexity*
G04C	Peritoneal Adhesiolysis, Minor Complexity*
G05C	Minor Small and Large Bowel Procedures
G10B	Hernia Procedures, Minor Complexity*
G11Z	Anal and Stomal Procedures
G47C	Gastroscopy, Minor Complexity**
G48A	Colonoscopy, Major Complexity*
G48B	Colonoscopy, Minor Complexity*
G48C	Colonoscopy, same day
H07A	Open Cholecystectomy, Major Complexity*
H08A	Laparoscopic Cholecystectomy, Major Complexity*
H06B	Other Hepatobiliary and Pancreas GIs, Intermediate Complexity*
H08B	Laparoscopic Cholecystectomy, Minor Complexity*
K04A	Major procedures for obesity
K04B	Major procedures for obesity
K04Z	Major procedures for obesity
K10A	Revisional and Open Bariatric Procedures, Major Complexity**
K12Z	Other Bariatric Procedures*
T01C	Infectious and Parasitic Diseases W GIs, Minor Complexity*
X06B	Other Procedures for Other Injuries, Intermediate Complexity*
X63B	Sequelae of Treatment, Minor Complexity*
Z01B	Other Contacts W Health Services W GIs, Minor Complexity*
Z40Z	Other Contacts W Health Services W Endoscopy*

Source: Independent Hospital Pricing Authority, Australian Refined Diagnosis Related Groups Version (6.0-9.0)

Appendix 8.3: Health indices - General final consumption expenditure (GFCE) on hospitals and nursing homes (reference year 2014-15 = 100) †.

	2006-07	2007-08	2008-09	2009-10	2010-11	2011-12	2012-13	2013-14	2014-15
GFCE on hospitals and nursing homes	80.7	83.0	85.7	89.0	90.1	92.3	95.0	97.7	100.0*

†Sourced from *Australian Institute of Health and Welfare Health Expenditure Australia Report 2014-15*
*assume fiscal year 2015-16 at reference year =100.

Chapter 9: Summary and future directions.

Preface

As the health economics component of the National Health and Medical Research Council partnership project regarding bariatric surgery, this thesis presented an overview of the obesity epidemic, the increasing health and economic burden of obesity, and health economic impact of bariatric surgery as a treatment option for obesity locally in Tasmania, nationally, and internationally.

To achieve the research objectives of my PhD project, this thesis adopted a mixed-methods approach using quantitative and qualitative research methods, consistent with a call for health economists to implement mixed-methods policy-relevant research that is embedded in and derived from real-world policy settings [1, 2]. This thesis addressed key evidence gaps and provided much needed information regarding the health economics of obesity and bariatric surgery for people with obesity waiting for, and/or who had received bariatric surgery, the project partner, the health economics community, the healthcare systems and society by:

- Conducting a comprehensive systematic review and quality appraisal to provide critical baseline evidence of the key evidence gaps and common themes regarding the health economic evaluation and reporting of bariatric surgery nationally and internationally;
- Investigating the complex health-related quality of life needs of people waiting for and who had received bariatric surgery using a preferentially sensitive multi-attribute utility instrument to capture and assess psychosocial health;
- Using qualitative research methods to elicit crucial health economic impacts that would typically be omitted from current economic evaluation frameworks, or not fully understood with traditional quantitative research methods; and
- Investigating Australian Activity Based Funding resource use and costs of bariatric surgery pre- and postoperatively in the Tasmanian public hospital system.

9.1 Chapter summary of this thesis

Overall, this thesis identified and addressed key knowledge gaps in the health economics reporting of bariatric surgery including the under-reporting of complications and reoperations following primary bariatric surgery and the identification of crucial psychosocial health-related quality of life impacts of bariatric surgery. The section below provides a chapter-by-chapter summary of this thesis. Section 9.2 then provides an integrated summary of this thesis and the key contributions to the science including recommendations (section 9.2.1) to our project partners and the health economics community.

Chapter 1 provided an overview of the health economics of obesity and bariatric surgery, and health economics as an important and separate discipline. Health economics guides scarce healthcare resource allocation from one treatment modality to another in the complex and competitive rationing process of healthcare budgets.

Chapter 1 stated that against a multifactorial background of a worldwide epidemic, obesity is a profoundly complex economic problem [3]. Demand far outstrips supply for bariatric surgery locally, national and internationally and decision makers who allocate resource-constrained healthcare budgets are forced to consider competing alternatives of treatments for obesity, including bariatric surgery [4, 5]. Within this epidemiological and economic climate of demand already far outstripping supply for bariatric surgery, severe obesity is increasing rapidly and the economic burden of Class 2 and Class 3 obesity is significantly higher than obesity [6]. Additionally, a greater prevalence of obesity is observed in more disadvantaged groups and these groups are generally not privately insured for their healthcare [7, 8]. These important health economic characteristics suggest that future patient prioritisation of bariatric surgery in public healthcare systems will become even more challenging within resource-constrained healthcare systems.

The societal economic impacts of obesity are a fundamental health economic consideration including work productivity [9-13], and personal and family impacts arising from discrimination and stigmatisation of the overweight and obese both individually and collectively, poorer relationships and social engagement [14, 15], however, most health economic studies regarding bariatric surgery ignore crucial societal considerations [4].

The nationally and internationally prevalent bariatric surgical procedure is laparoscopic sleeve gastrectomy [16], however, in Tasmania the most common procedure is laparoscopic adjustable gastric banding [7]. There is much current debate about the device-related complication and reoperation rates for laparoscopic adjustable gastric band surgery [17, 18]. Bariatric surgery is an efficacious and cost-effective treatment for severe and resistant obesity, nevertheless, this thesis' comprehensive systematic review (Chapter 2) established that most health economic evaluations of bariatric surgery are based on the narrow payer perspective (rather than a broader societal perspective), narrowly defined direct medical costs, if included (only 30%) the costs of complications and reoperations adopt a short timeframe or assumed a probability of the event occurring as low, short time horizons for analyses are prevalent, and administrative data sources inform most studies [19]. Psychosocial health status is a vital consideration for people with obesity who are waiting for and who undergo bariatric surgery [20, 21, 19]. This thesis' systematic review established that the EQ-5D is the most prevalent instrument in cost-utility analyses of bariatric surgery, however, only one of the instrument's five items assesses psychosocial health [4, 22].

Departures from mainstream neoclassical theory by health economists turns out to have been the territory in which some of the most innovative ideas of health economics have been generated [23]. Nevertheless, the concepts and tools of health economic evaluation are fundamental to many key health economic resource allocation decisions worldwide [24]. The basic tasks of any economic evaluation are to *identify*, measure, value and compare the costs and consequences of the alternatives being considered [24, 25]. Health economic evaluation of bariatric surgery mostly employ a narrow spectrum of costs and consequences for analyses [4].

There is a paucity of qualitative research in health economics, where qualitative research methods could enrich health economics research methodology and improve health economics practice [1]. Additionally, reporting in numbers and not words is encouraged within the mainstream neoclassical paradigm that considers sophisticated mathematical technique as the work of the scientific inquiry [1, 26].

In summary, Chapter 1's general overview highlighted that the prevalence of severe obesity is increasing and the obesity epidemic is costing more both directly and indirectly. Chapter 1 also revealed health economic evaluations that employ a wider scope of costs and consequences that reach well-beyond direct medical costs and administrative databases for their data inputs are needed. Additional allocation of scarce healthcare resources to bariatric surgery (particularly publicly-funded bariatric surgery) could be further motivated by health economic evaluations that employ a wider range of costs and consequences of bariatric surgery. Holistically, this thesis has substantially extended the scope of the costs and consequences that are considered in the health economic evaluation of bariatric surgery.

A published comprehensive systematic review of the global health economic literature pertaining to the economic evaluation of bariatric surgery was provided in Chapter 2 [4]. This review identified 77 published papers containing health economic data from partial and full economic evaluations of bariatric surgery. As an important alternative to previously published systematic reviews regarding bariatric surgery, this study did not seek to capture homogenous studies for meta-analysis to inform a further cost-effectiveness study: as an important and much needed alternative, this study aimed to adopt a broader approach with a view to identifying common themes and key evidence gaps across the depth and breadth of the health economic evaluation of bariatric surgery.

Importantly, this systematic review established that most studies employed a narrow payer perspective and were based on a limited spectrum of data input (mostly direct medical costs, and cost-utility studies were dominated by the EQ-5D multi-attribute utility instrument). A common theme was that bariatric surgery for severely obese people with type 2 diabetes is cost-effective (and even cost-saving). Only one study investigated the health economic impact of waiting for surgery. Chapter 2 called for a more comprehensive investigation and reporting of health economic outcomes of bariatric surgery to identify aspects of the bariatric surgery patient's journey that reached well beyond the primary surgery's direct medical costs. The review recommended that there is a need for studies that assume a broader societal perspective (including out-of-pocket costs, costs to family and productivity losses) and longer-term costs (capture reoperations/complications, waiting for surgery, body contouring), and consequences (health-related quality-of-life). The important evidence gaps identified in Chapter 2's systematic review regarding current knowledge and understanding of health economic evaluation of bariatric surgery informed the direction of the subsequent PhD projects of this thesis, part of the work program for the NHMRC partnership project, and future directions for research beyond this thesis.

Published Chapters 3, 4 and 5 of this thesis investigated the health-related quality of life for people waiting for (public system, longitudinal [19, 21]) and who then received bariatric surgery, and people who had received bariatric surgery many years previously (private system, cross-sectional [20]). This integrated suite of health-related quality of life studies were the first studies to systematically select two vastly different multi-attribute utility instruments (namely the EQ-5D-5L an internationally prevalent instrument that is dominant in the cost-utility analyses of bariatric surgery [4], and the AQoL-8D that is underpinned by psychometric principles and testing [27, 28]). The studies systematically compared the two instruments and identified robust health state utility valuations (both instruments), and individual and super dimension scores (AQoL-8D only) for the bariatric surgery study population.

Chapter 3 of this thesis was the first study to reveal that people who had received bariatric surgery many years previously (in the private sector) whom reported perfect health on the EQ-5D-5L (health state utility valuation of 1.0) rated themselves on the AQoL-8D as having a health state utility valuation of mean (standard deviation) 0.87 (0.08) [20]. This alternate valuation reported by the same participants for the AQoL-8D was driven by the instrument's individual domains of psychosocial health. These participants recorded a low score of 0.52 (0.13) for the Psychosocial super dimension (a composite measure of Happiness, Coping, Self-worth, Relationships and Mental Health) [20].

Chapter 2 of this thesis identified that only one health economic study investigated the impact of waiting for surgery [4]. Chapters 4 and 5 of this thesis were the first studies to use the EQ-5D-5L and AQoL-8D for a unique cohort of long-term publicly waitlisted patients who then received bariatric surgery due to a public policy decision to reduce waiting lists. One of the main findings of these studies was that the preoperative AQoL-8D health state utility valuation for this subgroup of bariatric surgery patients was less than those of people with cancer or heart disease. Even three months, and then 12 months after bariatric surgery, long-term publicly waitlisted patients recorded significant and clinically meaningful health-related quality of life improvements. This crucial result suggested that long-waiting patients should not be 'written-off' by healthcare decision makers: they can still realise significant improvements in health-related quality of life outcomes when ultimately treated, and this should be factored into patient prioritisation decisions.

In summary, the AQoL-8D's health state utility valuations reported in this integrated and published health-related quality of life suite of studies were the most robust reported to date because they have captured and assessed psychosocial health for the bariatric surgery study population. These health state utility valuations can be used to populate future health economic models for bariatric surgery. Additionally, there is an emerging literature regarding the use of patient-reported outcomes in the clinical setting and the health state utility valuations and individual and super dimension scores derived in Chapters 3, 4 and 5 could be employed for comparisons.

Chapter 6 presented one of two studies that used qualitative research methods to investigate the experiences of people waiting for, or who had received bariatric surgery. Over the past decade there has been a call for health economists to effectively integrate combinations of qualitative and quantitative methods into their research toolkit to enrich their research methodologies and therefore improve their practice in health economic study design, data gathering and analysis, reporting and ultimately research translation. Chapter 2's published systematic review identified the limited scope of costs and consequences for most health economic evaluation and subsequent reporting of bariatric surgery [4]. The review recommended a more comprehensive investigation and reporting of health economic outcomes of bariatric surgery to identify aspects of the bariatric surgery patient's journey that reached well beyond the primary surgery's direct medical costs [4]. Additionally, Chapters 3, 4 and 5 established that psychosocial health is a vital consideration for people who are waiting for and then undergo bariatric surgery [20, 19, 21]. Chapter 6 of this thesis employed qualitative research methods to listen to patients. By listening to patients' experiences this thesis identified the new concept of emotional capital where patients described life-changing desires to be productive and participate in their communities postoperatively. This thesis also established that after self-funding bariatric surgery, some patients experienced financial distress.

The new concept of emotional capital identified in Chapter 6 as a key consideration for health economic evaluation of bariatric surgery particularly consolidates the findings of Chapters 3, 4 and 5 of this thesis that identified psychosocial health as a vital consideration for people waiting for or who undergo bariatric surgery. To improve health economics practice, this thesis recommended a mixed-methods approach to the economic evaluation of bariatric surgery from model conceptualisation through to the separate reporting of qualitative findings to supplement the quantitative findings.

Chapter 7 also adopted the qualitative method and investigated the emergence of the concept of demand-induced supply in the information-age for people waiting for or who undergo bariatric surgery. Does demand-induce supply exist in the marketplace of bariatric surgery? Are bariatric surgery patients more information-savvy in the information-age? Chapter 7's study established that psychosocial or socio-emotional drivers informed the sources and types of information that were important to patients preoperatively. The study also found that information sources relevant to patients preoperatively (e.g. family and friends, and the Internet) were different postoperatively (surgeon, allied-health professionals e.g. psychologist).

Chapter 7 recommended that high-quality and consistent information sources be targeted towards the psychosocial domains of health for bariatric surgery patients preoperatively and ongoing postoperatively. The study also recommended that appropriate healthcare information be provided to enable a smoother transition for the management of physical health impacts such as postoperative dehydration and electrolyte imbalance which can result in unexpected hospitalisation: smoother postoperative transition would likely translate to a reduced burden on the healthcare dollar.

Chapter 8 is the final study of this mixed methods thesis. This quantitative health economics study has provided our project partner with accurate episode-of-care changes, resource use and cost analyses regarding the provision of bariatric surgery in the Tasmanian public hospital system that were not known. Chapter 8's inpatient patient-level outcomes, resource use costing study is the first study within the Australian public hospital setting to report on individual episodes-of-care and costed patient-level pathways for primary bariatric surgery, and subsequent surgical sequelae including secondary/tertiary surgery informed by Australia's Independent Hospital Pricing Authority's Activity Based Funding model. Chapter 2 of this thesis particularly guided the study's investigation of the patient-level unit costs, the costs of waiting for bariatric surgery, subgroup analyses (patients with diabetes and cardiovascular disease), and the accurate cost of complications and reoperations over a long time horizon. Chapter 8 found that the cost of providing the primary laparoscopic adjustable gastric band bariatric procedure compared with the sleeve gastrectomy procedure is similar. The study also suggested that prevalent laparoscopic adjustable gastric band device-related costs could be mitigated with alternative surgical methods such as sleeve gastrectomy (rather than the prevalent laparoscopic adjustable gastric band) within the Tasmanian public hospital system. Subgroup analyses revealed that for people with diabetes, the average cost for an episode-of-care reduced from the first year after surgery. The accurate and broad scope of patient-level and real-world cost data reported in this study can be used to populate future health economic models for bariatric surgery.

9.2 Integrated conclusions of this thesis

At the commencement of the NHMRC partnership project regarding bariatric surgery, our Tasmanian State Government partner stated that 'the burden of morbid obesity on individuals, government and society is unclear and the allocation of public resources to bariatric surgery lacks a strong evidence base'. Therefore, the key objective of this PhD research was to address these pressing health economic knowledge and policy gaps for people with obesity waiting for, and/or who had received bariatric surgery, our project partners, the health economics community, the healthcare systems and society.

In response to the key evidence gaps and principal research aims of this thesis outlined in Chapter 1 sections 1.7 and 1.8, as the health economist within the NHMRC partnership project this research found that the health economics reporting of costs and quality of life for bariatric surgery were deficient and this PhD research has addressed both key information gaps. This PhD thesis employed the AQoL-8D multi-attribute utility instrument and adopted qualitative research methods to elicit the psychosocial and emotional health needs of the study population. Psychosocial and emotional health are paramount considerations for people seeking bariatric surgery and for the success of their surgery. Through the development of a strategic alliance with our project partner, this PhD research provided much needed information to our project partner regarding the costs of bariatric surgery in Tasmania, the complication and reoperation rate and cost, the benefits for people with diabetes and cardiovascular disease, and preliminary information regarding the benefits of sleeve gastrectomy versus laparoscopic adjustable gastric banding. This research suggests that bariatric surgery is an attractive value-based option for people with severe and morbid obesity in Tasmania, and particularly for subgroups of patients such as people with T2DM. Preliminary evidence from this research also suggested that sleeve gastrectomy could be a cost-saving option, compared to laparoscopic adjustable gastric band surgery and that a larger confirmatory study of disaggregated costs should be conducted.More specifically, the principal conclusions of this thesis regarding the health economics of obesity and bariatric surgery were:

- There is disparate health economic evaluation and reporting of bariatric surgery of inconsistent quality. Partial and full health economic evaluations of bariatric surgery generally populate their models with a narrow spectrum of short-term direct medical cost data regarding the primary surgery only from administrative databases;
- Overall, this thesis provided a broader economic perspective regarding bariatric surgery as a treatment option for obesity;
- Health economic evaluation of bariatric surgery generally finds that bariatric surgery is cost-effective, and even cost-saving for people with type 2 diabetes who are severely obese;
- As an important emerging subgroup of bariatric surgery patients, there is a paucity of health economic analyses of costs and consequences for long-term publicly waitlisted patients in an environment of multiyear wait times where severe obesity is increasing rapidly for people in areas of lower socioeconomic disadvantage who do not have private health insurance;
- Why does the health economics community use the EQ-5D for the bariatric surgery study population? The AQoL-8D is preferentially sensitive regarding psychosocial health for the study population and this crucial finding has implications for downstream cost-utility analyses of bariatric surgery;
- Psychosocial health status is crucial for people waiting for and who then undergo bariatric surgery;

- Long-term waitlisted patients preoperative health state utility valuations are substantially diminished and comparable to patients undergoing cancer treatment or patients with severe cardiovascular disease;
- Long-term waitlisted patients realise significant health state utility valuation improvements (and individual and super dimension scores for the AQoL-8D) even three months after bariatric surgery suggesting that these patients should not be 'written-off' by healthcare planners if significant health benefits can be realised when they are ultimately treated;
- Qualitative research methods revealed the importance of emotional capital and out-of-pocket costs, and the sources and types of information before and after bariatric surgery.
- Qualitative research methods should supplement quantitative methods to elicit nuanced and detailed analysis of the health economic impact regarding bariatric surgery;
- Health economists should employ a mixed-methods approach to the economic evaluation of bariatric surgery from model conceptualisation through to the separate reporting of qualitative findings to supplement the quantitative findings; and
- Patient-level Tasmanian public hospital inpatient episodes-of-care, resource use and cost analyses provided much needed information regarding the resource use costs of bariatric surgery to the Tasmanian public hospital system. Bariatric surgery in the Tasmanian public hospital system may be an attractive value-based option in the longer term: bariatric surgery realised health benefits (reduced inpatient episodes-of-care) and reduced costs at year 3 postoperatively. The costs for publicly-waitlisted severely obese patients waiting for bariatric surgery who are then treated patients in Tasmania's public hospital system start decreasing at year three. Laparoscopic adjustable gastric band

device-related costs could be mitigated if replaced with sleeve gastrectomy bariatric surgery where clinically appropriate.

Holistically, this thesis has substantially extended the scope of the costs and consequences that have been considered in the health economic evaluation of bariatric surgery. The evidence gaps identified in Chapter 2's systematic review regarding current knowledge and understanding of health economic evaluation of bariatric surgery informed the direction of the subsequent PhD projects of this thesis. Chapter 2 called for a more comprehensive investigation and reporting of health economic outcomes of bariatric surgery to identify aspects of the bariatric surgery patient's journey that reached well beyond the primary surgery's direct medical costs. Chapter 2 recommended that there is a need for studies that assume a broader societal perspective (including out-of-pocket costs, costs to family and productivity losses) and longer-term costs (capture reoperations/complications, waiting for surgery, body contouring), and consequences (health-related quality-of-life). Chapters 3 to 8 of this thesis have addressed all of these key evidence gaps.

Severe obesity is increasing rapidly particularly in areas of socioeconomic disadvantage where people do not purchase private health insurance. Public places for bariatric surgery compete with life-saving cancer treatment, sick children, multiple trauma accidents, dementia care, end-of-life care, and the list goes on. Unfortunately, for our society health economic choices need to be made: the healthcare budget is finite. Moreover, public (and to some extent private) healthcare budgets are also allocated on political grounds – politics and policy are inextricably linked and the political allocation of scarce healthcare resources on a particular day may favour one alternative over another due to many competing interests including news' coverage – not the cost/QALY or any other health economics metric. Nevertheless, in this challenging and constantly evolving environment where there is a 'pragmatic tension' between the best-practice evidence-based health economics research and the realities of the policy and political environments, it is incumbent upon the health economist to convince the decision-maker that their research addresses the key evidence gaps in a relevant, accessible, and timely way: that the research is useful.

Our project partner has stated that the findings from this PhD thesis are of policy-changing interest, particularly when the findings of Chapter 8 are pooled with the findings and recommendations of my PhD research's investigation regarding the health economic evaluation of bariatric surgery (Chapter 2), the assessment of health-related quality of life for people waiting for or who had received bariatric surgery in the public and private healthcare systems (Chapters 3, 4 and 5) and the qualitative research regarding bariatric surgery patients' lived experiences (Chapters 6 and 7).

9.2.1 Key recommendations

This thesis' key recommendations align with the objectives of this thesis outlined in Chapter 1. This research recommends that:

- Given the evidence gaps identified by the thesis regarding the health economic reporting of bariatric surgery, this thesis recommends that studies assume a broader cost base, longer time horizon and societal perspective. Additionally, studies regarding people with diabetes and Class I Obesity should investigate the cost-effectiveness or even cost-saving of bariatric surgery;
- Appropriate choice of a multi-attribute utility instrument (e.g. AQoL-8D) to capture and assess the complex physical and psychosocial needs for people waiting for and who have received bariatric surgery;
- Prioritisation decisions regarding long term and severely obese long-term waitlisted

bariatric surgery patients should factor the psychosocial and emotional health-related quality of life impacts of the surgery into patient prioritisation decisions;

- Wherever possible, use qualitative research methods in the health economic reporting of bariatric surgery to identify important costs and consequences to validate and supplement quantitative results; and
- From a Tasmanian, perspective, bariatric surgery is an attractive value-based proposition for people waiting for bariatric surgery in the Tasmanian public hospital system. Sleeve gastrectomy should be considered as a treatment alternative where clinically indicated.

The next section of this thesis highlights the most promising key areas for future directions that have emerged from this PhD research and thesis.

9.3 Key areas for future directions and research translation

Chapters 2 to 8 of this PhD thesis have separately described promising opportunities for future directions. Further detail regarding some of these key opportunities for future directions are outlined in detail below.

9.3.1 Health economic evaluation

(i) Use the findings of this thesis to conduct a larger confirmatory study regarding sleeve gastrectomy as the preferred type of bariatric surgery when clinically appropriate.

Chapter 8 of this thesis revealed some promising evidence regarding sleeve gastrectomy as an attractive value-based proposition for the Tasmanian public health system. A larger confirmatory study is indicated that compares the costs and episodes-of-care for sleeve gastrectomy versus laparoscopic adjustable gastric banding, particularly the costs of complications and reoperations.

(ii) Use the findings of this thesis to populate a cost-utility model for bariatric surgery that adopts a broader perspective

Chapter 2 of this thesis highlighted the need for health economic evaluations of bariatric surgery that employ a wider scope of cost data, and that most cost-utility studies adopt health state utility valuations derived from the EQ-5D. Holistically, Chapters 3 to 8 of this thesis provided both quantitative and qualitative health economic analyses that explored a wider range of costs and consequence of bariatric surgery as a treatment option for obesity. These new results provide much needed data for a cost-utility analyses of bariatric surgery that adopts a broader societal perspective and beyond with the supplementary qualitative findings.

Chapter 8 provided real-world patient-level cost data (including subgroup analyses of people with diabetes and cardiovascular disease) before (for waitlisted patients) and after laparoscopic adjustable gastric band and sleeve gastrectomy bariatric surgery. These costs are informed by Australia's Activity Based Funding model and include accurate patient-level rates and costs of complications and reoperations of bariatric surgery. Chapters 3, 4 and 5 derived robust health state utility valuations that captured and assessed the complex physical and psychosocial health-related quality of life needs for severely obese patients who are waiting for and then undergo bariatric surgery. Chapters 6 and 7 derived qualitative results regarding out-of-pocket costs and emotional capital that led to productivity and participation.

This thesis is the first tranche of health economics analyses for the NHMRC partnership project regarding obesity and bariatric surgery. A new health economics PhD candidate will commence on the NHMRC partnership project in December 2017. This mixed-methods thesis provides robust quantitative data to populate a real-world cost-utility model for the broader NHMRC project and our project partner. This mixed-methods thesis also provides much needed qualitative data generated from listening to patients. The qualitative data will provide crucial information for the conceptualisation and construction of the model. The qualitative data will also supplement the cost-utility results.

(iii) Advocate for mixed-methods research in health economics to improve practice in economic evaluation of bariatric surgery

Reviewer comments to Chapter 6 of this thesis stated:

> *'I completely agree with, and commend the author's on their research seeking to advance the use of mixed methods research, and particularly their efforts to advance the use of qualitative input into economic evaluation. It is crucially important that economic evaluation output is patient relevant, and the current study seeks to address an important gap in the literature. As the authors quite correctly acknowledge the use of mixed methods research is too often ignored in the economic evaluation literature, and this is particularly*

true in bariatric surgery.'

This thesis advocated for mixed-methods research in health economics for both health economic evaluation model conceptualisation and construction, and for qualitative results to be reported to the policy decision-maker as supplementary information – in words and not numbers.

I will continue to advocate for mixed-methods research in health economics.

9.3.2 Health-related quality of life

(i) Scoring the EQ-5D-5L with an Australian algorithm

An important area for future research is scoring the EQ-5D-5L with an Australian algorithm. This will enable further work to be done to compare this instrument with the AQoL-8D.

(ii) Explore a revised EQ-5D-5L with a bolt-on item/s for emotional capital and test against the AQoL-8D

Chapters 3, 4 and 5 of this thesis identified that, compared to the EQ-5D-5L, the AQoL-8D preferentially captured and assessed the complex psychosocial health for bariatric surgery patients who had received their bariatric surgery many years previously in the private system (Chapter 3) and for long-term publicly waitlisted patients who then received bariatric surgery (Chapters 4 and 5).

Chapter 6 identified a new concept of emotional capital for people who were waiting for or had received bariatric surgery. One of the reviewers stated that the concept of emotional capital was 'enticing and convincing' and suggested that the entire manuscript should explore the concept of emotional capital 'that would hold true for many patient groups' not just for bariatric surgery but for other disease processes such as diagnosis of a life-threatening condition, or for people with a seriously sick child. This reviewer also asked for concrete suggestions where emotional capital could or should become part of some revised form of the EQ-5D.

Chapter 6 included the requested revisions and also explored the recent literature that raised concerns regarding these bolt-on items to the EQ-5D (including the concerns that were raised in Chapter 3). Notwithstanding these qualifications and in accordance with the revised manuscript contained in Chapter 6, my PhD thesis recommends that a promising area for future research is the development of an 'emotional capital' bolt-on item/s for the EQ-5D-5L.

A bolt-on item should also be tested against the AQoL-8D multi-attribute utility instrument and follow the methods that I have developed in my two published head-to-head comparison papers [20, 21].

(iii) Explore emotional capital for other disease processes

As mentioned in point 9.3.2 (i), the concept of emotional capital would hold true for many disease processes and a promising area for future directions would be to explore this crucial new concept, particularly for other chronic diseases. One of the reviewers for Chapter 6 made the point that emotional capital could apply to many disease processes for patients and their carers including 'parents with a seriously sick child and people waiting for an organ transplant'.

(iv) Explore the predictive capabilities of the AQoL-8D

As an independent measure of health-related quality of life, there is emerging literature that suggests health state utility valuations could be independent predictors of health outcomes. Prediction is more likely to be accurate when the instrument used for prediction takes account of the full range of the complex physical and psychosocial health domains associated with the problem. This thesis found that the AQoL-8D is more likely to provide correct prediction than the EQ-5D-5L for the bariatric surgery study population.

Therefore, the area of clinical prediction using the AQoL-8D for the bariatric surgery study population is a promising area for future research.

(v) Compare the AQoL-8D with the SF-6D for bariatric surgery

An important area for future research suggested in Chapter 4 of this thesis was that the AQL-8D could be compared against the SF-6D. Comparison for long-term waitlisted patients who then receive bariatric surgery would be useful, given that this thesis found that the health state utility valuations for these patients preoperatively are comparable to people with cancer or heart disease.

(vi) Advocate for the inclusion of the AQoL-8D in the International Society for Pharmacoeconomics Outcomes Research (ISPOR) teaching materials

International workshops regarding patient-reported outcomes are convened by ISPOR. Interestingly, these workshops (including the Asia-Pacific workshop) do not include any materials regarding the AQoL-8D and instead advocate the use of the EQ-5D-5L and other prevalent instruments such as the SF-6D. These materials could be more balanced by providing health economists with the opportunity to explore the multi-attribute utility instrument that is informed by psychometric principles and testing.

(vii) Advocate for qualitative research methods to improve health economics practice

Overall, there is a critical need for health economists to enrich their research methodologies with qualitative methods. This is an important area for future directions – the publication of Chapter 6 in the world leading journal *Health Economics* will enable the author of this thesis to facilitate this message.

9.3.3 The provision of bariatric surgery in Tasmania

Overall, the findings of this thesis suggest that providing bariatric surgery in Tasmania is efficient and that severely obese waitlisted patients should not be written off by healthcare planners because they can still realise significant health benefits when ultimately treated.

Our project partner has stated that the findings from this PhD thesis are of policy-changing interest. The costs of providing bariatric surgery in Tasmania are lower than comparable national and international published estimates; even after Tasmanian costs for secondary surgery are included. As outlined above, a robust cost-utility study will be the subject of future directions for our project partner.

Our project partner has also suggested that the comparison of sleeve gastrectomy and laparoscopic adjustable gastric band surgery is of policy-changing interest because it would mitigate the cost of device-related costs for banding.

The strategic research alliance created in Chapter 8 for the real-world costing study will be the subject of a further policy study. Lessons learnt from the alliance will inform some of the future directions for more collaborative work with the critical health partner.

Postscript

During my PhD research I have been tremendously fortunate to be provided with the opportunity to collaborate with and learn from such a dedicated and scholarly team that comprises academic researchers from wide-ranging disciplines, clinicians, government policy decision makers and allied-health practitioners.

I would encourage health economics PhD candidates to explore the opportunities that an applied partnership project within a multi-disciplinary team could bring to their learnings and research, and ultimately their research translation. Collectively, our multi-disciplinary team has worked hard to help people with severe obesity who are waiting for or who undergo bariatric surgery, to provide much needed information to healthcare planners about patient pathways and the costs and consequences of those pathways.

Ultimately, I hope that my research will help people with severe obesity who are waiting for or who undergo bariatric surgery, locally, nationally and internationally.

9.4 References

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Publications arising from this thesis

Chapter 2:

Campbell JA, .Venn A, Neil A, Hensher M, Sharman A and Palmer AJ. “Diverse approaches to the health economic evaluation of bariatric surgery: a comprehensive systematic review”. *Obesity Reviews*. 2016 Sep;17(9):850-94. doi: 10.1111/obr.12424. Epub 2016 Jul 7.

Chapter 3:

Campbell JA, Palmer AJ, **Venn** A, Sharman M, Otahal P, Neil A. “A Head-to-head Comparison of the EQ-5D-5L and AQoL-8D Multi-attribute Utility Instruments in Patients Who Have Previously Undergone Bariatric Surgery”. *The Patient – Patient Centered Outcomes Research.* 2016 Aug; 9(4):311-22. doi: 10.1007/s40271-015-0157-5

Chapter 4:

Campbell JA, Hensher M, Neil A, Venn A, Wilkinson S, and Palmer AJ. “An Exploratory Study of Long-Term Publicly Waitlisted Bariatric Surgery Patients’ Quality of Life Before and 1 Year After Bariatric Surgery, and Considerations for Healthcare Planners”. *PharmacoEconomics-Open*. 2017:1-4. doi:10.1007/s41669-017-0038-z

Chapter 5:

Campbell JA, Hensher M, Neil A, Venn A, Otahal P, Wilkinson S, and Palmer AJ. “An exploratory study: a head-to-head comparison of the EQ-5D-5L and AQoL-8D for long-term publicly waitlisted bariatric surgery patients before and 3 months after bariatric surgery”. *PharmacoEconomics – Open*. 2017. doi: 10.1007/s41669-017-0060-1

Chapter 6:

Campbell JA, Ezzy D Neil A, Hensher M, Venn A, Sharman MJ, and Palmer AJ. A qualitative investigation of the health economic impacts of bariatric surgery for obesity, and implications for improved practice in health economics. *Health Economics*. 2018 Aug;27(8):1300-1318.

Chapter 7:

Campbell JA, Ezzy D, Hensher M, Neil A, Venn A, Sharman MJ, Wilkinson S and Palmer AJ. "A qualitative investigation of information asymmetry for obesity surgery: diversity of patient experiences in the information age and demand-induced supply". This manuscript has been submitted to *PharmacoEconomics*.

Chapter 8:

Campbell JA, Hensher M, Davies D, Green M, Hagan B, Jordan I, Venn A, Kuzminov A, Neil A, Palmer AJ. "A cost-outcome study: A real-world investigation of long-term inpatient hospital utilisation and costs for a retrospective cohort of bariatric surgery patients in an Australian public hospital system based on Australia's Activity Based Funding model" This manuscript is under review at *PharmacoEconomics Open* and a request for revisions is being progressed..

Other publications

Sharman MJ, Hensher M, Wilkinson S, **Campbell JA**, Venn AJ. Review of publicly-funded bariatric surgery policy in Australia-lessons for more comprehensive policy making. *Obesity Surgery*. 2016;26(4):817–24.

Appendix 2: Conference presentations arising from this thesis

Oral presentations

2017 Australian Health Economics Society Doctoral Workshop, Sydney 20 September 2017. "A cost-outcome study: A real-world investigation of long-term inpatient hospital utilisation and costs for a retrospective cohort of bariatric surgery patients in an Australian public hospital system based on Australia's Activity Based Funding model".

Competitively selected as one of only six PhD Candidates or Postdoctoral Research Fellows from national and international applicants to present at this workshop.

2017 Catholic Health Australia, National Conference, Hobart, 29 August 2017. Invited speaker.
"The Health Economics of Obesity and Bariatric Surgery".

Letter of thanks received from the conference organisers.

2017 Menzies Centre for Health Policy, Emerging Health Policy Research Conference, Sydney, 28 July 2017.
"Bariatric Surgery: Investigating Health Service and Societal Costs and Consequences, Health Impacts and Policy Options".

2016 Australian Health Economics Society Conference, Perth, 26 September 2016.
"A qualitative investigation of the emergence of demand-induced supply for bariatric surgery: diversity of patient perspectives and implications for economic evaluation".

2015 Public Health Association of Australia, Population Health Congress, Hobart, 7 September 2015.
"A head-to-head comparison of the EQ-5D-5L and AQoL-8D multi-attribute utility instruments in patients who have undergone bariatric surgery".

Poster presentations

2016 International Society of PharmacoEconomics Outcomes Research: Asia-Pacific Conference, Singapore, 5 September 2016.

"A Unique Opportunity To Assess Quality-Of-Life Changes In Long-Term Waitlisted Bariatric Surgery Patients Using The Eq-5d-5l And AQol-8D Multi-Attribute Utility Instruments Before And Three Months After Bariatric Surgery: An Exploratory Study".

Awarded a 'Poster Finalist Award' at the conference.

2015 9th Health Services Research Association of Australia and New Zealand, Health Services Policy Conference, Melbourne, 8 December 2015.

A head-to-head comparison of the EQ-5D-5L and AQoL-8D multi-attribute utility instruments in patients who have undergone bariatric surgery".

2014 University of Tasmania Higher Degree Research Conference, Hobart, September 2014.

"A comprehensive systematic review of the health economic evaluation of bariatric surgery".